ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: September 17, 2021

ClinicalTrials.gov ID: NCT02919306

Study Identification

Unique Protocol ID:	CR108161
Brief Title:	Safety and Efficacy Study of Vaccine Schedule With Ad26.Mos.HIV and MVA-Mosaic in Human Immunodeficiency Virus (HIV)-Infected Adults
Official Title:	A Combined Phase 1/2a, Exploratory Study of a Therapeutic Vaccine Using an Adenovirus Type 26 Vector Prime and Modified Vaccinia Ankara Boost Combination With Mosaic Inserts in HIV-1 Infected Adults Who Initiated Antiretroviral Treatment During Acute HIV Infection
Secondary IDs:	VAC89220HTX1001 [Janssen Vaccines & Prevention B.V.]

Study Status

Record Verification:	September 2021
Overall Status:	Completed
Study Start:	September 2016 [Actual]
Primary Completion:	September 2018 [Actual]
Study Completion:	September 2018 [Actual]

Sponsor/Collaborators

Sponsor:	Janssen Vaccines & Prevention B.V.
Responsible Party:	Sponsor
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: 22 Dec 2015 Board Name: Institutional Review Board, Faculty of Medicine, Chulalongkom University Board Affiliation: Institutional Review Board, Faculty of Medicine, Chulalongkom University Phone: +662564493 Email: Address: 1873 Rama 4 Road, Pathumwan, Bangkok, 10330, Thailand
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	The purpose of the study is to assess: 1 safety and tolerability of adenovirus serotype 26 (Ad26) prime and Modified Vaccinia Ankara (MVA) boost versus placebo in participants on suppressive antiretroviral therapy (ART) that was initiated during acute Human Immunodeficiency Virus (HIV) infection; 2) Measure the frequency and duration of sustained viremic control after receiving Ad26 prime/MVA boost or placebo, defined as greater than 24 weeks with plasma HIV ribonucleic acid (RNA) lesser than (<)50 copies/ml after antiretroviral (ARV) analytical treatment interruption (ATI).
Detailed Description:	

Conditions

Conditions:	Human Immunodeficiency Virus
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase:	Phase 1/Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double (Participant, Investigator)
Allocation:	Randomized
Enrollment:	27 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Ad26.Mos.HIV Vaccine or MVA mosaic Vaccine Participants will receive adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (containing 5 * 10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Week 24 and 48.	Biological/Vaccine: Ad26.Mos.HIV Recombinant replication-deficient Ad26 vectored vaccine and consists of 3 Ad26 vectors, one containing a mosaic insert of envelope (Env) sequence, and 2 vectors containing mosaic inserts of Gag and Pol sequences (Ad26.Mos.1.Env + Ad26.Mos1.Gag-Pol + Ad26.Mos2.Gag-Pol). Total dose is 5*10^10 viral particle per 0.5 milliliter (mL) injection administered intramuscularly. Biological/Vaccine: MVA-Mosaic Recombinant live attenuated MVA virus-vectored vaccine that has been genetically engineered to express 2 mosaic Gag, Pol, and Env sequences (Mosaic 1 and Mosaic 2). Total dose is 10^8 plaque-forming unit per 0.5 mL injection administered intramuscularly.
Placebo Comparator: Placebo 0.5 mL Sodium Chloride Injection United States Pharmacopeia (USP) 0.9% will be administered by intramuscular (IM) injection.	Drug: Placebo Participants will receive placebo intramuscularly Weeks 0, 12, 24 and 48.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	50 Years
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No

Criteria: Inclusion Criteria:

- Confirmed human immunodeficiency virus (HIV)-1 infected and started antiretroviral therapy (ART) during acute infection (Fiebig stages I, II, III or IV) as part of trial RV254
- Treatment with current stable antiretroviral therapy (ART) (no changes to treatment) for at least 4 weeks prior to screening
- All female participants of childbearing potential must have a negative serum pregnancy test (beta human chorionic gonadotropin) at the screening visit, and a negative urine pregnancy test prior to vaccination on Day 1 and prior to subsequent study vaccinations
- HIV ribonucleic acid (RNA) less than (<)50 copies per milliliter (copies/ml) for at least 48 weeks at screening: a) One blip of HIV RNA greater than (>)50 and <200 copies/ml within 48 weeks is acceptable, provided that the most recent (before screening) HIV RNA <50 copies/ml
- Laboratory criteria during screening: a) Hemoglobin: Women: greater than or equal to >=11 gram/deciliter (g/dL); Men >=12.5 g/dL, b) White cell count: 2,500 to 11,000 cells per cubic millimeter (cells/mm^3), c) Platelets: 125,000 to 450,000 per mm^3, d) Alanine aminotransferase (ALT)/aspartate aminotransferase (AST) less than or equal to <=1.5x institutional upper limits of normal (ULN), e) Creatinine <=1.5x institutional ULN, f) CD4 > 400 cells/mm^3, g) Troponin <1x ULN
- A woman must be either: a) Not of childbearing potential: postmenopausal (>45 years of age with amenorrhea for at least 2 years, or any age with amenorrhea for at least 6 months and a serum follicle stimulation hormone [FSH] level >40 International Units Per Liter (IU/L); surgically sterile; or b) Of child-bearing potential and practicing an effective double method of birth control (example, prescription oral contraceptives, contraceptive injections, intrauterine device, contraceptive patch, or vaginal ring, in conjunction with either a female condom or one of the methods for male contraception before entry and through 3 months after the last vaccination

Exclusion Criteria:

- Receipt of any vaccine within 30 days prior to the first vaccination or plans to receive within 30 days post-vaccination. In the case of medically indicated vaccines, the vaccination should be given at least 2 weeks before or after the first vaccination. However, if a vaccine is indicated in a post exposure setting (example, rabies or tetanus), it must take priority over the study vaccine and same rules will apply to subsequent study vaccinations
- Any history of HIV-related illness under Centers for Disease Control and Prevention (CDC) category C
- History of myocarditis, pericarditis, cardiomyopathy, congestive heart failure with permanent sequelae, clinically significant arrhythmia (including any arrhythmia requiring medication, treatment, or clinical follow-up)
- Chronic active hepatitis B or active hepatitis C (for example, positive serology with confirmatory positive polymerase chain reaction) or active syphilis infection. Active syphilis documented by examination or serology unless positive serology is due to past treated infection
- Receipt of blood products or immunoglobulin in the past 3 months
- History of anaphylaxis or other serious adverse reactions to vaccines or vaccine products, or neomycin or streptomycin or egg products
- History of chronic urticaria (recurrent hives)
- Chronic or recurrent use of medications which modify host immune response, example (e.g.) cancer chemotherapeutic agents, parenteral corticosteroids (short course oral steroids given for non-chronic conditions not expected to recur is not an exclusion criteria, topical steroid use is not an exclusion criteria), etc. but not including ART

Contacts/Locations

Central Contact Person: For more information, please email

Email: JNJ.CT@sylogent.com

Central Contact Backup:

Study Officials: Janssen Vaccines & Prevention B.V. Clinical Trial
Study Director
Janssen Vaccines & Prevention B.V.

Locations: **Thailand**
Bangkok, Thailand

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Documents

Study Protocol
Document Date: October 11, 2017
Uploaded: 09/17/2021 04:35

Statistical Analysis Plan
Document Date: October 17, 2018
Uploaded: 09/17/2021 04:35

Delayed Results

Delay Type	Certify Initial Approval
Intervention Name(s)	Ad26.Mos.HIV and MVA-Mosaic

Study Results

Participant Flow

Pre-assignment Details	Of the 37 participants screened for this study, 27 participants were randomized and received at least 1 dose of active vaccine (18 participants) or placebo (9 participants). One participant in the active vaccine group was excluded from the analysis on request of the Ethics Committee due to a major protocol deviation.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Overall Study

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Started	17	9
Completed	16	9
Not Completed	1	0

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Withdrawal by Subject	1	0

Baseline Characteristics

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Baseline Measures

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo	Total
Overall Number of Participants		17	9	26
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	17 participants	9 participants	26 participants
		27.4 (5.39)	26.3 (6.87)	27 (5.83)

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo	Total
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	9 participants	26 participants
	Female	0 0%	0 0%	0 0%
	Male	17 100%	9 100%	26 100%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	9 participants	26 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%
	Asian	17 100%	9 100%	26 100%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%
	Black or African American	0 0%	0 0%	0 0%
	White	0 0%	0 0%	0 0%
	More than one race	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%
Region of Enrollment Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	17 participants	9 participants	26 participants
THAILAND		17 100%	9 100%	26 100%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Grade 3 or 4 Solicited Local Adverse Events (AEs)
Measure Description	Solicited local AE of grade 3 or 4 and that is thought to be related to study vaccine were reported. An AE is any untoward medical occurrence in a clinical study participant administered a investigational or non-investigational medicinal product. An AE does not necessarily have a causal relationship with the treatment. Solicited local AEs (at injection site) included pain/tenderness, erythema, induration, swelling, itching and warmth were collected and reported for 7 days after each vaccination.
Time Frame	Up to Week 49 (7 days post each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With Grade 3 or 4 Solicited Local Adverse Events (AEs) Measure Type: Number Unit of measure: percentage of participants	0	0

2. Primary Outcome Measure:

Measure Title	Percentage of Participants With Grade 3 or 4 Solicited Systemic AEs
Measure Description	Solicited systemic AE of grade 3 or 4 and that is thought to be related to study vaccine were reported. Solicited systemic AEs included fever (defined as body temperature of 38.0-degree celsius or higher), fatigue, headache, myalgia, arthralgia, chills, nausea, vomiting, rashes, and general itching.
Time Frame	Up to Week 49 (7 days post each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/ mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With Grade 3 or 4 Solicited Systemic AEs Measure Type: Number Unit of measure: percentage of participants	0	0

3. Primary Outcome Measure:

Measure Title	Percentage of Participants With Grade 3 or 4 Unsolicited AEs
Measure Description	Unsolicited AE with worst severity grade 3 or 4 and that is thought to be related to study vaccine were reported. Unsolicited AEs were defined as events that participants experienced but were not specifically asked about.
Time Frame	Up to Week 52 (28 days after each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With Grade 3 or 4 Unsolicited AEs Measure Type: Number Unit of measure: percentage of participants	0	0

4. Primary Outcome Measure:

Measure Title	Percentage of Participants With Grade 3 or 4 Related AEs
Measure Description	Related AEs of grade 3 or 4 and that is thought to be related to study vaccine were reported.

Time Frame	Up to Week 52 (28 days after each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With Grade 3 or 4 Related AEs Measure Type: Number Unit of measure: percentage of participants	0	0

5. Primary Outcome Measure:

Measure Title	Percentage of Participants With Solicited Local AEs for 7 Days After Each Vaccination
Measure Description	An AE is any untoward medical occurrence in a clinical study participant administered a investigational or non-investigational medicinal product. An AE does not necessarily have a causal relationship with the treatment. Solicited local AEs (at injection site) included pain/tenderness, erythema, induration, swelling, itching and warmth were collected and reported for 7 days after each vaccination.
Time Frame	Up to Week 49 (7 days post each vaccination)

Analysis Population Description

The Full Analysis Set (FAS) included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Percentage of Participants With Solicited Local AEs for 7 Days After Each Vaccination Measure Type: Number Unit of measure: percentage of participants	88.2	66.7

6. Primary Outcome Measure:

Measure Title	Percentage of Participants With Solicited Systemic AEs for 7 Days After Each Vaccination
Measure Description	Solicited systemic AEs included fever (defined as body temperature of 38.0-degree celsius or higher), fatigue, headache, myalgia, arthralgia, chills, nausea, vomiting, rashes, and general itching were collected and reported for 7 days after each vaccination.
Time Frame	Up to Week 49 (7 days after each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/ mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With Solicited Systemic AEs for 7 Days After Each Vaccination Measure Type: Number Unit of measure: percentage of participants	70.6	55.6

7. Primary Outcome Measure:

Measure Title	Percentage of Participants With Unsolicited AEs 28 Days After Each Vaccination
Measure Description	Unsolicited AEs were defined as events that participants experienced but were not specifically asked about.
Time Frame	Up to Week 52 (28 days after each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With Unsolicited AEs 28 Days After Each Vaccination Measure Type: Number Unit of measure: percentage of participants	88.2	77.8

8. Primary Outcome Measure:

Measure Title	Percentage of Participants With Related AEs and Serious Adverse Events (SAEs)

Measure Description	An AE is any untoward medical occurrence in a clinical study participant administered a investigational or non-investigational medicinal product. An AE does not necessarily have a causal relationship with the treatment. A SAE is any AE that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect and is a suspected transmission of any infectious agent via a medicinal product.
Time Frame	Up to Week 52 (28 days after each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Percentage of Participants With Related AEs and Serious Adverse Events (SAEs) Measure Type: Number Unit of measure: percentage of participants		
Related AEs	29.4	0
Related SAEs	0	0

9. Primary Outcome Measure:

Measure Title	Percentage of Participants With AEs Leading to Discontinuation of Study Vaccination
Measure Description	Percentage of participants with AEs leading to discontinuation of study vaccination were reported.
Time Frame	Up to Week 96

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/ mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With AEs Leading to Discontinuation of Study Vaccination Measure Type: Number Unit of measure: percentage of participants	0	0

10. Primary Outcome Measure:

Measure Title	Percentage of Participants With AEs
Measure Description	Percentage of participants with AEs were reported.
Time Frame	Up to Week 52 (28 days after each vaccination)

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo. The data was planned for unsolicited AEs during the 28-day post-vaccination phase.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With AEs Measure Type: Number Unit of measure: percentage of participants	88.2	77.8

11. Primary Outcome Measure:

Measure Title	Percentage of Participants With Worst Laboratory Toxicity Grades 1, 2, 3, and 4 and Non-graded Serum Chemistry Abnormalities

Measure Description	Percentage of participants with worst laboratory grades 1 (mild), 2 (moderate), 3 (severe), and 4 (potentially life-threatening) and non-graded serum chemistry abnormalities were reported. Serum chemistry parameters included alanine aminotransferase, aspartate aminotransferase, creatine, hyperglycemia, hypoglycemia, gamma-gutamyl transferase, chloride, urea nitrogen, and bilirubin. The parameters not represented in the grading scale, abnormalities were indicated as being 'high' or 'low' or 'abnormal'.
Time Frame	Up to Week 96

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo. Here 'n' (number analyzed) signifies number of participants evaluable for specified categories.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Percentage of Participants With Worst Laboratory Toxicity Grades 1, 2, 3, and 4 and Non-graded Serum Chemistry Abnormalities Measure Type: Number Unit of measure: percentage of participants	[Not specified]		
Post-Any Dose: Alanine Aminotransferase- Grade 1	Number Analyzed	17 participants	9 participants
		50	0
Post-Any Dose: Alanine Aminotransferase- Grade 3	Number Analyzed	17 participants	9 participants
		50	0
Post-Any Dose: Aspartate Aminotransferase- Grade 1	Number Analyzed	17 participants	9 participants
		50	0
Post-Any Dose: Aspartate Aminotransferase- Grade 4	Number Analyzed	17 participants	9 participants
		50	0
ART resumption: Alanine Aminotransferase- Grade 1	Number Analyzed	16 participants	8 participants
		12.5	12.5
ART resumption: Aspartate Aminotransferase- Grade 1	Number Analyzed	16 participants	8 participants
		12.5	37.5
ART resumption: Creatine- Grade 1	Number Analyzed	16 participants	8 participants
		12.5	25
ART resumption: Hyperglycemia- Grade 1	Number Analyzed	16 participants	8 participants
		6.3	0
ART resumption: Hyperglycemia- Grade 2	Number Analyzed	16 participants	8 participants
		6.3	0

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
ART resumption: Hypoglycemia- Grade 1	Number Analyzed	16 participants	8 participants
		0	12.5
ART resumption: Hypoglycemia- Grade 2	Number Analyzed	16 participants	8 participants
		6.3	0
ATP: Gamma Glutamyl Transferase (high)	Number Analyzed	17 participants	9 participants
		5.9	11.1
ATP: Gamma Glutamyl Transferase (low)	Number Analyzed	17 participants	9 participants
		0	11.1
ART resumption: Chloride (High)	Number Analyzed	16 participants	8 participants
		18.8	12.5
ART resumption: Urea Nitrogen (Low)	Number Analyzed	16 participants	8 participants
		12.5	0
ART Resumption: Bilirubin	Number Analyzed	16 participants	8 participants
		0	12.5

12. Primary Outcome Measure:

Measure Title	Percentage of Participants With Worst Laboratory Toxicity Grade 1 and Non-graded Hematology Abnormalities
Measure Description	Percentage of participants with worst laboratory toxicity grade 1 (mild) and non-graded hematology abnormalities were reported. Hematology parameters included absolute neutrophil count, basophils/leukocytes, eosinophils/leukocytes, hematocrit, lymphocytes/leukocytes, monocytes/leukocytes, neutrophils/leukocytes, erythrocytes, hematocrit, neutrophils, basophils, eosinophils, eosinophils/leukocytes, monocytes, neutrophils and platelet count. The parameters not represented in the grading scale, abnormalities were indicated as being ‘high’ or ‘low’ or ‘abnormal’.
Time Frame	Up to Week 96

Analysis Population Description

FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo. Here 'n' (number analyzed) signifies number of participants evaluable for specified categories.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed		17	9
Percentage of Participants With Worst Laboratory Toxicity Grade 1 and Non-graded Hematology Abnormalities Measure Type: Number Unit of measure: percentage of participants	[Not specified]		

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
ART resumption: Absolute Neutrophil Count-Grade 1	Number Analyzed	17 participants	8 participants
		0	12.5
Post-Any Dose: Basophils/Leukocytes (high)	Number Analyzed	17 participants	9 participants
		11.8	0
Post-Any Dose: Eosinophils/Leukocytes (high)	Number Analyzed	17 participants	9 participants
		5.9	11.1
Post-Any Dose: Hematocrit (low)	Number Analyzed	17 participants	9 participants
		5.9	11.1
Post-Any Dose: Lymphocytes/Leukocytes (high)	Number Analyzed	17 participants	9 participants
		0	11.1
Post-Any Dose: Lymphocytes/Leukocytes (low)	Number Analyzed	17 participants	9 participants
		5.9	0
Post-Any Dose: Monocytes/Leukocytes (high)	Number Analyzed	17 participants	9 participants
		5.9	11.1
Post-Any Dose: Neutrophils/Leukocytes (low)	Number Analyzed	17 participants	9 participants
		5.9	11.1
ATI: Eosinophils/ Leukocytes (high)	Number Analyzed	17 participants	9 participants
		0	33.3
ATI: Eosinophils/ Leukocytes (low)	Number Analyzed	17 participants	9 participants
		0	11.1
ATI: Erythrocytes (low)	Number Analyzed	17 participants	9 participants
		17.6	11.1
ATI: Hematocrit (low)	Number Analyzed	17 participants	9 participants
		23.5	11.1
ATI: Lymphocytes/ Leukocytes (high)	Number Analyzed	17 participants	9 participants

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
		5.9	22.2
ATI: Lymphocytes/ Leukocytes (low)	Number Analyzed	17 participants	9 participants
		0	11.1
ATI: Monocytes/ Leukocytes (high)	Number Analyzed	17 participants	9 participants
		35.3	44.4
ATI: Neutrophils (low)	Number Analyzed	17 participants	9 participants
		11.8	11.1
ATI: Neutrophils/ Leukocytes (low)	Number Analyzed	17 participants	9 participants
		5.9	22.2
ART resumption: Basophils (high)	Number Analyzed	17 participants	8 participants
		0	12.5
ART resumption: Basophils/Leukocytes (high)	Number Analyzed	17 participants	8 participants
		11.8	25
ART resumption: Eosinophils (high)	Number Analyzed	17 participants	8 participants
		0	12.5
ART resumption: Eosinophils (low)	Number Analyzed	17 participants	8 participants
		17.6	12.5
ART resumption: Eosinophils/Leukocytes (high)	Number Analyzed	17 participants	8 participants
		11.8	37.5
ART resumption: Eosinophils/Leukocytes (low)	Number Analyzed	17 participants	8 participants
		17.6	12.5
ART resumption: Erythrocytes (high)	Number Analyzed	17 participants	9 participants
		5.9	0
ART resumption: Erythrocytes (low)	Number Analyzed	17 participants	9 participants
		11.8	12.5
ART resumption: Hematocrit (low)	Number Analyzed	17 participants	8 participants

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
		29.4	12.5
ART resumption: Lymphocytes/Leukocytes (high)	Number Analyzed	17 participants	8 participants
		17.6	25
ART resumption: Lymphocytes/Leukocytes (low)	Number Analyzed	17 participants	8 participants
		11.8	0
ART resumption: Monocytes/Leukocytes (high)	Number Analyzed	17 participants	8 participants
		64.7	50
ART resumption: Monocytes (high)	Number Analyzed	17 participants	9 participants
		11.8	0
ART resumption: Neutrophils (low)	Number Analyzed	17 participants	8 participants
		41.2	12.5
ART resumption: Neutrophils/Leukocytes (high)	Number Analyzed	17 participants	8 participants
		0	12.5
ART resumption: Neutrophils/Leukocytes (low)	Number Analyzed	17 participants	8 participants
		29.4	25
Platelet count	Number Analyzed	17 participants	9 participants
		0	0

13. Primary Outcome Measure:

Measure Title	Percentage of Participants With Sustained Viremic Control (Human Immunodeficiency Virus [HIV] Ribonucleic Acid [RNA] Less Than [<]50 Copies Per Milliliter [Copies/mL]) During ATI Phase
Measure Description	Percentage of participants with sustained viremic control (HIV RNA <50 copies/mL) during ATI phase were reported.
Time Frame	From Week 60 to Week 96

Analysis Population Description

The primary Efficacy Population (EP) included all participants who started antiretroviral (ARV) ATI at Week 60 and interrupted at least one dose of ART (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Participants With Sustained Viremic Control (Human Immunodeficiency Virus [HIV] Ribonucleic Acid [RNA] Less Than [<]50 Copies Per Milliliter [Copies/mL]) During ATI Phase Measure Type: Number Unit of measure: percentage of participants	0	11.1

14. Primary Outcome Measure:

Measure Title	Duration of Sustained Viremic Control With HIV RNA <50 Copies/mL During ATI Phase
Measure Description	Duration of sustained viremic control With HIV RNA <50 copies/mL during ATI Phase was reported.
Time Frame	From Week 60 to Week 96

Analysis Population Description

The primary EP included all participants who started ARV ATI at Week 60 and interrupted at least one dose of ART (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Duration of Sustained Viremic Control With HIV RNA <50 Copies/mL During ATI Phase Mean (95% Confidence Interval) Unit of measure: weeks	3.1 (2.47 to 3.77)	1.9 (1.67 to 2.19)

15. Secondary Outcome Measure:

Measure Title	Total HIV Deoxyribonucleic Acid (DNA) Levels Over Time
Measure Description	The total HIV DNA levels were assessed as a biomarker of the HIV reservoir.
Time Frame	From Week 60 to Week 96

Analysis Population Description

The primary EP included all participants who started ARV ATI at Week 60 and interrupted at least one dose of ART (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Total HIV Deoxyribonucleic Acid (DNA) Levels Over Time Mean (Standard Deviation) Unit of measure: copies/10E6 cells		
Start of ATI	34.83 (54.04)	80.10 (117.36)
6 Months post ATI	47.24 (67.49)	80.00 (72.52)

16. Secondary Outcome Measure:

Measure Title	Change in Cluster of Differentiation (CD)4 Count Over Time
Measure Description	Change in CD4 count over time was reported. Assessment of residual HIV replication and viral reservoir in total CD4+ T cells was measured by quantitative real-time polymerase chain reaction (PCR).
Time Frame	Baseline and from Week 60 to Week 96

Analysis Population Description

The primary EP included all participants who started ARV ATI at Week 60 and interrupted at least one dose of ART (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Change in Cluster of Differentiation (CD)4 Count Over Time Median (Inter-Quartile Range) Unit of measure: Cells per cubic milliliters (cells/mm^3)		
Baseline	637 (NA to NA) [1]	531 (NA to NA) [2]
ATI	602 (NA to NA) [2]	498 (NA to NA) [2]
ART	661 (NA to NA) [2]	616 (NA to NA) [2]
Week 96	620 (NA to NA) [2]	538 (NA to NA) [2]

[1] Inter-Quartile Range (IQR) was not calculated as data were sparse and not normally distributed and the IQR is not a meaningful descriptor of non-normal data.

[2] IQR was not calculated as data were sparse and not normally distributed and the IQR is not a meaningful descriptor of non-normal data.

17. Secondary Outcome Measure:

Measure Title	Time to Reinitiating ART
Measure Description	Time to reinitiating ART was reported.
Time Frame	Up to Week 96

Analysis Population Description

The primary EP included all participants who started ARV ATI at Week 60 (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Time to Reinitiating ART Mean (95% Confidence Interval) Unit of measure: Weeks	5.4 (4.64 to 6.18)	4.5 (3.14 to 5.93)

18. Secondary Outcome Measure:

Measure Title	Number of Participants With Acute Retroviral Syndrome Post-ARV ATI
Measure Description	Number of participants with acute retroviral syndrome post-ARV ATI were reported.
Time Frame	From Week 60 to Week 96

Analysis Population Description

The primary EP included all participants who started ARV ATI at Week 60 and interrupted at least one dose of ART (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/ mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Number of Participants With Acute Retroviral Syndrome Post-ARV ATI Measure Type: Count of Participants Unit of measure: participants	0 0%	0 0%

19. Secondary Outcome Measure:

Measure Title	Duration of Acute Retroviral Syndrome Post-ARV ATI
Measure Description	Duration of acute retroviral syndrome post-ARV ATI was reported.
Time Frame	From Week 60 to Week 96

Analysis Population Description

The primary EP included all participants who started ARV ATI at Week 60 and interrupted at least one dose of ART (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Duration of Acute Retroviral Syndrome Post-ARV ATI Median (Full Range) Unit of measure: weeks	NA (NA to NA) [1]	NA (NA to NA) [1]

[1] No acute retroviral syndrome was reported during the study.

20. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HIV Resistance to ARV Drugs Who Experienced Rebound Viremia After ARV ATI

Measure Description	Percentage of participants with HIV resistance to ARV drugs who experienced rebound viremia after ARV ATI were reported. An HIV genotype test was done to evaluate and characterize HIV resistance to ARV drugs in participants who experience rebound viremia after ARV ATI.
Time Frame	From Week 60 to Week 96

Analysis Population Description

The primary EP included all participants who started ARV ATI at Week 60 and interrupted at least one dose of ART (Stage 2), regardless of the time or outcome of treatment interruption.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Percentage of Participants With HIV Resistance to ARV Drugs Who Experienced Rebound Viremia After ARV ATI Measure Type: Number Unit of measure: percentage of participants	35.3	22.2

21. Secondary Outcome Measure:

Measure Title	Percentage of Responders With Interferon-gamma (IFN-gamma) T Cell Responses Analyzed by Enzyme-linked Immunospot Assay (ELISpot) at Week 24, 26, 48, and 50
Measure Description	Frozen peripheral blood mononuclear cell (PBMCs) was analyzed by interferon-gamma (IFN-gamma) (ELISpot). The response was defined as post-baseline value >P95 if baseline <P95 or missing or defined as post-baseline value >3-fold increase from baseline if baseline >=P95. The threshold for ELISpot test was based on the 95th percentile (P95) from the baseline values of participants on that test in the study.
Time Frame	At Week 24, 26, 48 and 50

Analysis Population Description

The Immunogenicity Population (IP) included all participants who were randomized and received at least 3 vaccinations according to the protocol-specified vaccination schedule, excluding the participant with a major protocol deviation. Here 'n' (number analyzed) signifies number of participants evaluable at specified time points.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/ mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed		17	9
Percentage of Responders With Interferon-gamma (IFN-gamma) T Cell Responses Analyzed by Enzyme-linked Immunospot Assay (ELISpot) at Week 24, 26, 48, and 50 Measure Type: Number Unit of measure: percentage of responders	[Not specified]		
HIV IFNg ENV pep pool (Clinical PTE): Week 24	Number Analyzed	17 participants	9 participants
		70.6	11.1
HIV IFNg ENV pep pool (Clinical PTE): Week 26	Number Analyzed	17 participants	9 participants
		100	22.2
HIV IFNg ENV pep pool (Clinical PTE): Week 48	Number Analyzed	17 participants	9 participants
		70.6	22.2
HIV IFNg ENV pep pool (Clinical PTE): Week 50	Number Analyzed	15 participants	7 participants
		80.0	0
HIV IFNg ENV pep pool (Mos1): Week 26	Number Analyzed	17 participants	9 participants

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
		94.1	0
HIV IFNg ENV pep pool (Mos1): Week 50	Number Analyzed	15 participants	7 participants
		100	0
HIV IFNg ENV pep pool (Mos2): Week 26	Number Analyzed	17 participants	9 participants
		58.8	0
HIV IFNg ENV pep pool (Mos2): Week 50	Number Analyzed	15 participants	7 participants
		66.7	0
HIV IFNg ENV10 pep subpool (PTE): Week 26	Number Analyzed	17 participants	9 participants
		11.8	0
HIV IFNg ENV10 pep subpool (PTE): Week 50	Number Analyzed	15 participants	7 participants
		20.0	0
HIV IFNg ENV11 pep subpool (Mos1): Week 26	Number Analyzed	17 participants	9 participants
		0	0
HIV IFNg ENV11 pep subpool (Mos1): Week 50	Number Analyzed	15 participants	7 participants
		0	0
HIV IFNg ENV11 pep subpool (Mos2): Week 26	Number Analyzed	14 participants	7 participants
		0	0
HIV IFNg ENV11 pep subpool (Mos2): Week 50	Number Analyzed	15 participants	7 participants
		0	0
HIV IFNg ENV11 pep subpool (PTE): Week 26	Number Analyzed	17 participants	9 participants
		11.8	0
HIV IFNg ENV11 pep subpool (PTE): Week 50	Number Analyzed	15 participants	7 participants
		0	0
HIV IFNg ENV12 pep subpool (Mos1): Week 26	Number Analyzed	17 participants	9 participants
		5.9	0
HIV IFNg ENV12 pep subpool (Mos1): Week 50	Number Analyzed	15 participants	7 participants
		0	0

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
HIV IFNg ENV12 pep subpool (Mos2): Week 26	Number Analyzed	14 participants	7 participants
		0	0
HIV IFNg ENV12 pep subpool (Mos2): Week 50	Number Analyzed	15 participants	7 participants
		0	0
HIV IFNg ENV12 pep subpool (PTE): Week 26	Number Analyzed	17 participants	9 participants
		11.8	0
HIV IFNg ENV12 pep subpool (PTE): Week 50	Number Analyzed	15 participants	7 participants
		6.7	0
HIV IFNg ENV13 pep subpool (Mos1): Week 26	Number Analyzed	17 participants	9 participants
		0	0
HIV IFNg ENV13 pep subpool (Mos1): Week 50	Number Analyzed	15 participants	7 participants
		0	0
HIV IFNg ENV13 pep subpool (Mos2): Week 26	Number Analyzed	14 participants	7 participants
		21.4	0
HIV IFNg ENV13 pep subpool (Mos2): Week 50	Number Analyzed	15 participants	7 participants
		6.7	0
HIV IFNg ENV13 pep subpool (PTE): Week 26	Number Analyzed	17 participants	9 participants
		5.9	0
HIV IFNg ENV13 pep subpool (PTE): Week 50	Number Analyzed	15 participants	7 participants
		0	0
HIV IFNg ENV14 pep subpool (Mos1): Week 26	Number Analyzed	17 participants	9 participants
		17.6	0
HIV IFNg ENV14 pep subpool (Mos1): Week 50	Number Analyzed	15 participants	7 participants
		20.0	0
HIV IFNg ENV14 pep subpool (Mos2): Week 26	Number Analyzed	14 participants	7 participants
		14.3	0
HIV IFNg ENV14 pep subpool (Mos2): Week 50	Number Analyzed	15 participants	7 participants

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
		6.7	0

22. Secondary Outcome Measure:

Measure Title	Percentage of Responders for Envelop (Env) Clade A, B, C and Mos1-specific Binding Antibody Titers
Measure Description	The Env Clade A (92UG037), B (1990a), and C (Con C), (C97ZA.012) and Mos1- specific binding antibody titer were assessed using enzyme-linked immunosorbent assay (ELISA). The response was defined as post-baseline value greater than (>) lower limit of quantification (LLOQ) if baseline less than (<) LLOQ or missing or defined as post-baseline value >3-fold increase from baseline if baseline greater than or equal to (>=) LLOQ. The lower limits of quantification (LLOQs) for this assay were 625, 156.25, 625, 156.25 and 78.125 endotoxin units per milliliter (EU/mL) for Clade A (92UG037), Clade B (1990a), Clade C (Con C), Clade C (C97ZA.012) and Mos1 respectively.
Time Frame	At Week 24, 26, 48 and 50

Analysis Population Description

The IP included all participants who were randomized and received at least 3 vaccinations according to the protocol-specified vaccination schedule, excluding the participant with a major protocol deviation.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Responders for Envelop (Env) Clade A, B, C and Mos1-specific Binding Antibody Titers Measure Type: Number Unit of measure: percentage of responders		
HIV ENV (gp140 T) A (92UG037.1) IgG-t Ab: Week 24	100	11.1
HIV ENV (gp140 T) A (92UG037.1) IgG-t Ab: Week 26	100	0
HIV ENV (gp140 T) A (92UG037.1) IgG-t Ab: Week 48	94.1	11.1
HIV ENV (gp140 T) A (92UG037.1) IgG-t Ab: Week 50	100	0
HIV ENV (gp140 T) B (1990a) IgG-t Ab: Week 24	100	0
HIV ENV (gp140 T) B (1990a) IgG-t Ab: Week 26	100	0
HIV ENV (gp140 T) B (1990a) IgG-t Ab: Week 48	100	0
HIV ENV (gp140 T) B (1990a) IgG-t Ab: Week 50	100	0
HIV ENV (gp140 T) C (ConC) IgG-t Ab: Week 24	94.1	0
HIV ENV (gp140 T) C (ConC) IgG-t Ab: Week 26	70.6	0
HIV ENV (gp140 T) C (ConC) IgG-t Ab: Week 48	82.4	0
HIV ENV (gp140 T) C (ConC) IgG-t Ab: Week 50	94.1	0
HIV ENV (gp140 T) C (ZA) IgG-t Ab: Week 4	76.5	0
HIV ENV (gp140 T) C (ZA) IgG-t Ab: Week 16	82.4	0
HIV ENV (gp140 T) C (ZA) IgG-t Ab: Week 24	82.4	0

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
HIV ENV (gp140 T) C (ZA) IgG-t Ab: Week 26	82.4	0
HIV ENV (gp140 T) C (ZA) IgG-t Ab; Week 48	64.7	0
HIV ENV (gp140 T) C (ZA) IgG-t Ab: Week 50	76.5	0
HIV ENV (gp140 T) Mos1 IgG-t Ab: Week 24	88.2	0
HIV ENV (gp140 T) Mos1 IgG-t Ab; Week 26	100	0
HIV ENV (gp140 T) Mos1 IgG-t Ab: Week 48	94.1	0
HIV ENV (gp140 T) Mos1 IgG-t Ab: Week 50	94.1	0

23. Secondary Outcome Measure:

Measure Title	Percentage of Responders for Clade C (C97ZA.012) Env ELISA Immunoglobulin G1 (IgG1), IgG2, IgG3 and IgG4 Glycoprotein (gp) 140 Binding Antibody
Measure Description	Vaccine-induced binding antibody IgG1, IgG2, IgG3 and IgG4 subclass responses were investigated using Clade C (C97ZA.012) specific ELISAs. The response was defined as post-baseline value >LLOQ if baseline <LLOQ or missing or defined as post-baseline value >3-fold increase from baseline if baseline >=LLOQ. The LLOQs for this assay were 12.3, 28.7, 12.4, and 13.2 for IgG1, IgG2, IgG3 and IgG4, respectively. Less participants were assessed for IgG2 responses due to lack of sample volume which led to a limit on the number of repeats that the analysis lab could perform. Reportable results were not generated for the remaining participants post vaccination.
Time Frame	Week 50

Analysis Population Description

The IP included all participants who were randomized and received at least 3 vaccinations according to the protocol-specified vaccination schedule, excluding the participant with a major protocol deviation. Here 'n' (number analyzed) signifies number of participants evaluable at specified time points.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed		17	9
Percentage of Responders for Clade C (C97ZA.012) Env ELISA Immunoglobulin G1 (IgG1), IgG2, IgG3 and IgG4 Glycoprotein (gp) 140 Binding Antibody Measure Type: Number Unit of measure: percentage of responders	[Not specified]		

		Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
HIV ENV (gp140 T) clade C (ZA) IgG-1 Ab	Number Analyzed	16 participants	9 participants
		68.8	0
HIV ENV (gp140 T) clade C (ZA) IgG-2 Ab	Number Analyzed	3 participants	0 participants
		0	---
HIV ENV (gp140 T) clade C (ZA) IgG-3 Ab	Number Analyzed	16 participants	9 participants
		18.8	11.1

24. Secondary Outcome Measure:

Measure Title	Breadth of T Cell Responses Analyzed by ELISPOT Assays
Measure Description	Breadth of T cell responses was assessed at baseline (Week 0), Week 26, and Week 50 by ELISPOT assays.
Time Frame	Baseline (Week 0), Week 26 and 50

Analysis Population Description

The IP included all participants who were randomized and received at least 3 vaccinations according to the protocol-specified vaccination schedule, excluding the participant with a major protocol deviation.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/ mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Breadth of T Cell Responses Analyzed by ELISPOT Assays Median (Inter-Quartile Range) Unit of measure: Number of Subpools		
Baseline	2.0 (NA to NA) [1]	3.5 (NA to NA) [1]
Week 26	10.0 (NA to NA) [1]	3.0 (NA to NA) [1]
Week 50	8.0 (NA to NA) [1]	3.0 (NA to NA) [1]

[1] IQR was not calculated as data were sparse and not normally distributed and the IQR is not a meaningful descriptor of non-normal data.

25. Secondary Outcome Measure:

Measure Title	Percentage of Env Antibody-dependent Cellular Phagocytosis (ADCP) Glycoprotein (gp) Antibody Over Time
Measure Description	The functionality of vaccine-induced antibody responses was investigated by the determination of ADCP. The response was defined as post-baseline value > limit of detection (LOD) if baseline <LOD or missing or defined as post-baseline value >3-fold increase from baseline if baseline >=LOD. The lower limits of detection (LODs) for this assay were 5.16, 6.43, 6.49, 4.32 and 4.28 (phagocytic score) for Clade A (92UG037), Clade B (1990a), Clade C (Con C), Clade C (C97ZA.012), and Mos1, respectively.
Time Frame	At Week 24, 26, 48 and 50

Analysis Population Description

The IP included all participants who were randomized and received at least 3 vaccinations according to the protocol-specified vaccination schedule, excluding the participant with a major protocol deviation.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Env Antibody-dependent Cellular Phagocytosis (ADCP) Glycoprotein (gp) Antibody Over Time Median (Full Range) Unit of measure: percentage of ADCP gp antibody		
Week 24	4.500 (0.00 to 37.60)	0 (0.00 to 1.00)
Week 26	18.200 (0 to 50.00)	0 (0 to 0.80)

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Week 48	10.500 (0.0 to 44.20)	0 (0 to 1.80)
Week 50	20.500 (0 to 49.00)	0 (0 to 12.90)

26. Secondary Outcome Measure:

Measure Title	Percentage of Responders for HIV Neutralizing Antibody (nAb)
Measure Description	The functionality of vaccine-induced antibody responses was investigated by the determination of nAb activity in a virus neutralization assay (VNA) using TZM-bl cells and Env-pseudotyped viruses. The response was defined as post-baseline value >LLOQ.
Time Frame	Week 64

Analysis Population Description

The IP included all participants who were randomized and received at least 3 vaccinations according to the protocol-specified vaccination schedule, excluding the participant with a major protocol deviation.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.

	Description
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

Measured Values

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Placebo
Overall Number of Participants Analyzed	17	9
Percentage of Responders for HIV Neutralizing Antibody (nAb) Measure Type: Number Unit of measure: percentage of responders	100	0

Reported Adverse Events

Time Frame	Up to Week 96
Adverse Event Reporting Description	FAS included all participants who were randomized and who received at least 1 dose of study vaccine or placebo.

Reporting Groups

	Description
Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine	Participants from study NCT03032575, NCT01397669, NCT02475915, NCT02750059, and NCT00796146 who started on antiretroviral therapy (ART) during acute human immunodeficiency virus (HIV) infection, and who were on a current stable ART for at least 4 weeks prior to screening received adenovirus serotype 26-Mosaic -Human Immunodeficiency Virus (Ad26.Mos.HIV) 0.5 milliliter (mL) injection intramuscularly (IM) (containing 5*10^10 viral particles [vp]) at Weeks 0 and 12 followed by modified Vaccinia Ankara-Mosaic (MVA mosaic) 0.5 mL injection (containing 10^8 Plaque-forming unit [pfu]) at Weeks 24 and 48 (Stage 1). Participants who met immunologic response criteria (more than 50 percent [%] of vaccines had an increase of Interferon [IFN]-gamma producing cells) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an analytical treatment interruption (ATI) was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) more than (>) 1,000 copies per milliliters (copies/mL) twice at least 1 week apart or cluster of differentiation (CD) 4+ T cell counts less than (<) 350 per cubic millimeter (350/mm^3) twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96.
Placebo	Participants from study RV254 who started on ART during acute HIV infection, who were on a current stable ART for at least 4 weeks prior to screening received placebo IM injection at Weeks 0, 12, 24, and 48 (Stage 1). Participants who met immunologic response criteria (more than 50% vaccines had an increase of IFN-gamma producing cells in the vaccine arm) (36 weeks of follow-up) were verified at Week 60 (Stage 2). For eligible participants, an ATI was started and all ARTs were discontinued. Participants had to reinitiate ART after ATI using the same regimen as their previous treatment (before Week 60) when HIV-1 RNA >1,000 copies/mL twice at least 1 week apart or CD 4+ T cell counts <350/mm^3 twice at least 2 weeks apart or CD4+ T cell count decline of > 50% from Week 60 prior to ATI up to Week 96. up to Week 96.

All-Cause Mortality

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total All-Cause Mortality	0/17 (0%)		0/9 (0%)	

Serious Adverse Events

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	1/17 (5.88%)		0/9 (0%)	
Cardiac disorders				
Palpitations [A] *	1/17 (5.88%)		0/9 (0%)	
Tachycardia [A] *	1/17 (5.88%)	1	0/9 (0%)	0

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
General disorders				
Pyrexia [A] *	1/17 (5.88%)		0/9 (0%)	

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA Version 21.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	15/17 (88.24%)		7/9 (77.78%)	
Blood and lymphatic system disorders				
Lymphadenopathy [A] *	1/17 (5.88%)		0/9 (0%)	
Gastrointestinal disorders				
Abdominal Distension [A] *	1/17 (5.88%)		0/9 (0%)	
Anogenital Dysplasia [A] *	1/17 (5.88%)		1/9 (11.11%)	
Diarrhoea [A] *	1/17 (5.88%)		0/9 (0%)	
General disorders				
Feeling Hot [A] *	3/17 (17.65%)		0/9 (0%)	
Pyrexia [A] *	1/17 (5.88%)		2/9 (22.22%)	
Immune system disorders				
Food Allergy [A] *	0/17 (0%)		1/9 (11.11%)	
Infections and infestations				
Anal Chlamydia Infection [A] *	1/17 (5.88%)		0/9 (0%)	
Chlamydial Infection [A] *	1/17 (5.88%)		0/9 (0%)	
Nasopharyngitis [A] *	1/17 (5.88%)		1/9 (11.11%)	
Oropharyngeal Gonococcal Infection [A] *	0/17 (0%)		1/9 (11.11%)	

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Pharyngitis [A] *	0/17 (0%)		1/9 (11.11%)	
Rhinitis [A] *	0/17 (0%)		1/9 (11.11%)	
Subcutaneous Abscess [A] *	0/17 (0%)		1/9 (11.11%)	
Syphilis [A] *	1/17 (5.88%)		1/9 (11.11%)	
Upper Respiratory Tract Infection [A] *	4/17 (23.53%)		1/9 (11.11%)	
Urethritis [A] *	0/17 (0%)		1/9 (11.11%)	
Urethritis Chlamydial [A] *	0/17 (0%)		1/9 (11.11%)	
Injury, poisoning and procedural complications				
Animal Bite [A] *	1/17 (5.88%)		0/9 (0%)	
Skin Abrasion [A] *	0/17 (0%)		1/9 (11.11%)	
Investigations				
Cd4 Lymphocytes Decreased [A] *	1/17 (5.88%)		0/9 (0%)	
Hepatic Enzyme Increased [A] *	1/17 (5.88%)		0/9 (0%)	
Liver Function Test Increased [A] *	3/17 (17.65%)		0/9 (0%)	
Weight Decreased [A] *	1/17 (5.88%)		0/9 (0%)	
Metabolism and nutrition disorders				
Abnormal Loss of Weight [A] *	0/17 (0%)		1/9 (11.11%)	
Folate Deficiency [A] *	1/17 (5.88%)		0/9 (0%)	
Hypophagia [A] *	1/17 (5.88%)		0/9 (0%)	
Musculoskeletal and connective tissue disorders				
Myalgia [A] *	1/17 (5.88%)		0/9 (0%)	
Nervous system disorders				
Dizziness [A] *	2/17 (11.76%)		0/9 (0%)	

	Ad26.Mos.HIV Vaccine or MVA Mosaic Vaccine		Placebo	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Headache [A] *	1/17 (5.88%)		1/9 (11.11%)	
Respiratory, thoracic and mediastinal disorders				
Cough [A] *	1/17 (5.88%)		0/9 (0%)	
Dyspnoea [A] *	1/17 (5.88%)		0/9 (0%)	
Nasal Congestion [A] *	1/17 (5.88%)		0/9 (0%)	
Rhinitis Allergic [A] *	2/17 (11.76%)		0/9 (0%)	
Skin and subcutaneous tissue disorders				
Dermatitis Contact [A] *	1/17 (5.88%)		0/9 (0%)	
Rash [A] *	1/17 (5.88%)		0/9 (0%)	

***** Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 21.0

Limitations and Caveats

Subgroup analyses were performed by Ad26 baseline seropositivity for the humoral (ie, binding antibody responses; Env ELISA IgG-t gp140) and cellular immune responses (ie, IFN T cell responses and epitope mapping), and by time to rebound (3 tertile subgroups) for both the humoral and cellular immune responses (all parameters). Due to the low number of participants in each subgroup, no firm conclusions could be made.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

If an investigator wishes to publish information from the study, a copy of the manuscript must be provided to the sponsor for review at least 60 days before submission for publication or presentation.

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