Clinical Results Summary

A study to learn about the effects and safety of ruxolitinib cream in adolescents and adults with eczema

Also known as: TRuE-AD2

Thank you!

We thank participants for taking part or allowing their child to take part in this research study ("study") for ruxolitinib cream. Their time and commitment have helped us try to bring new medicines to patients.

CONTENTS

Important: This summary only shows the results of this single study. Other studies using the same drug may have different results. Researchers and health authorities look at the results of many studies to understand how treatments work and if there are any safety concerns. It takes many studies around the world to advance medical science and healthcare. Please do not use the results of this one study to make any healthcare decisions for yourself, or for your family and friends. Talk to your doctor or study doctor before changing any treatment you are taking or if you have any questions about the results of this study.

1. Why was this study done?

Researchers were looking for different ways to treat atopic dermatitis, also known as eczema. Some of the most common symptoms that people with eczema may have are dry, red, and itchy patches on the skin that can crack and weep. There can be other symptoms of eczema as well, but they are not listed here.

This was a Phase 3 study*.

* In Phase 3 studies, the study drug is given to a large number of participants with a disease or condition to learn more about how well the study drug works and how safe it is.

The main question the researchers wanted to answer in this study was:

How many participants had improvement in eczema as assessed by the study doctor after 8 weeks of treatment?

There were some additional questions that researchers wanted to answer, but these are not discussed in this summary. This information can be found using the internet links provided at the end of this document.

2. Which drug was studied?

Participants received either ruxolitinib cream or vehicle cream. Participants were put into 3 groups (2 groups received different strengths of ruxolitinib cream and 1 group received vehicle cream) randomly to minimize differences between groups.

Ruxolitinib cream: Incyte Corporation (the "sponsor") was studying ruxolitinib cream for the treatment of eczema. It is a cream that is applied to the affected area of the skin. The focus of this study was on 2 ruxolitinib cream strengths: 0.75% and 1.5%.

Vehicle cream: Vehicle cream looked like ruxolitinib cream and was applied in the same way but did not have any medication in it. Researchers sometimes use a vehicle to understand if changes that occurred were due to the study drug or if they happened by chance.

In this study, neither the participants nor the researchers knew who was given which drug. Studies are sometimes done this way to make sure that study results are not biased by this information.

This study had 2 parts:

Part 1 of the study, also called the **vehicle-controlled (VC) period**, tested how the treatment works on eczema. Participants were put into 3 groups randomly (like drawing straws). This helps to minimize differences across the groups. Participants applied either the 0.75% or 1.5% strength of ruxolitinib cream or vehicle cream twice a day for 8 weeks. Participants who completed Part 1 of the study and did not have any safety issues that the study doctor was concerned about could continue with the next part.

Part 2 of the study, also called the **long-term safety (LTS) period**, checked how safe the treatment was over 44 more weeks. All participants applied either the 0.75% or 1.5% strength of ruxolitinib cream twice a day. However, unlike Part 1, they could stop treatment if their skin cleared and restart treatment if their symptoms reappeared. Participants who got ruxolitinib cream during Part 1 continued the same treatment. Participants who got vehicle cream during Part 1 were then randomly re-assigned to receive either the 0.75% or 1.5% strength of ruxolitinib cream.

3. Who could take part in this study?

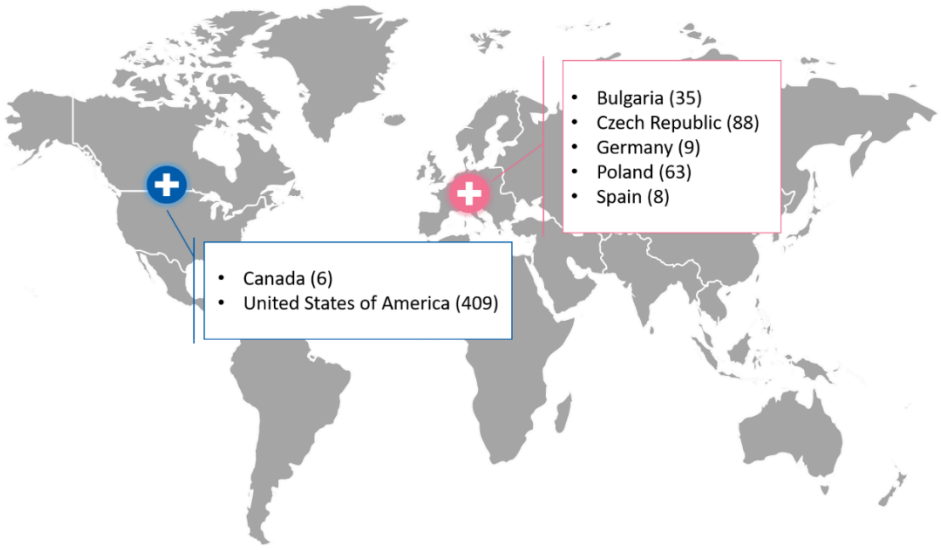
People could take part in this study if they:

- ✓ were at least 12 years of age;
- ✓ were diagnosed with eczema by a medical professional at least 2 years before starting the study;
- ✓ had mild to moderate eczema; and
- ✓ had 3% to 20% of their body area, excluding the scalp, affected by eczema.

There were other conditions participants had to fulfill to join this study. Visit the websites listed at the end of this summary for more information.

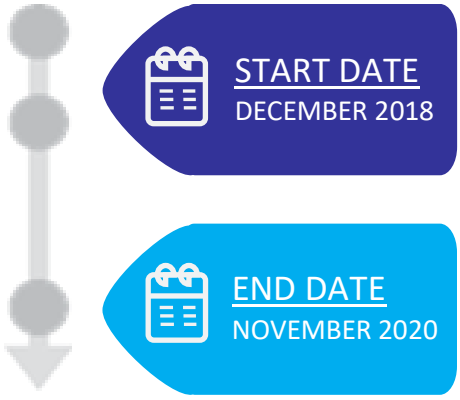
4. Who participated in this study?

This study included 618 participants from 7 countries.



This study included adolescent and adult men and women with eczema between the ages of 12 and 85 years. 20% of participants (122 out of 618) were 12 to 17 years old.

5. When was this study done?



The study started in December 2018 and ended in November 2020. When the study ended, the researchers created a report of the study results that were available. This summary is based on that report.

6. What were the overall results of this study?

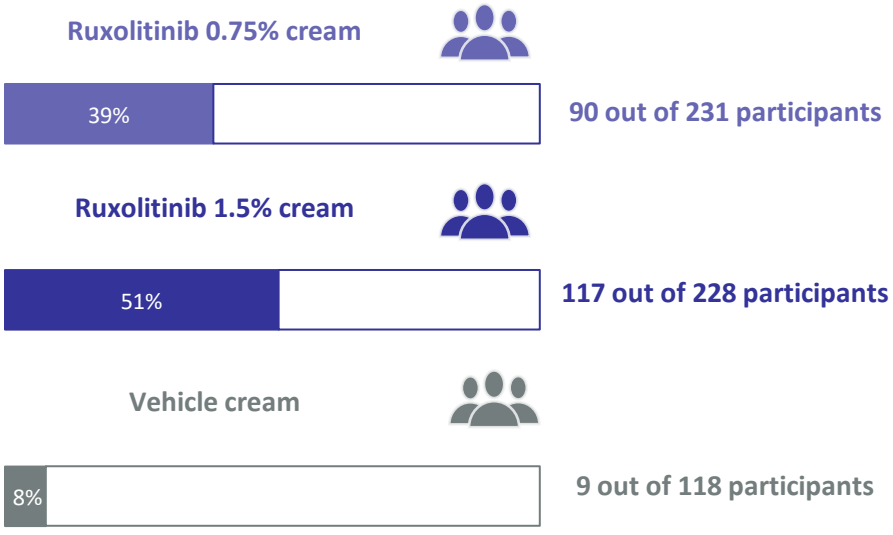
Key results from this study are shown for each study group of participants collectively. This summary does not show the results of each individual participant. An individual participant's results could be different from those of the total group of participants.

How many participants had improvement in eczema as assessed by the study doctor after 8 weeks of treatment?

Researchers measured the severity of eczema by looking at the area affected by eczema on the participants' bodies and, based on the appearance, scored it on 2 standard scales: Investigator Global Assessment (IGA) and Eczema Area and Severity Index (EASI).

In North America, IGA is the standard scale used for measuring the severity of eczema. Using this scale, researchers looked at the number of participants who had clear skin or almost clear skin after 8 weeks of twice-a-day treatment. This meant that participants had an IGA score of 0 or 1 on a scale of 0-4. Results of this study after 8 weeks of treatment showed that more participants in the ruxolitinib cream groups had clear or almost clear skin compared to the participants in the vehicle cream group.

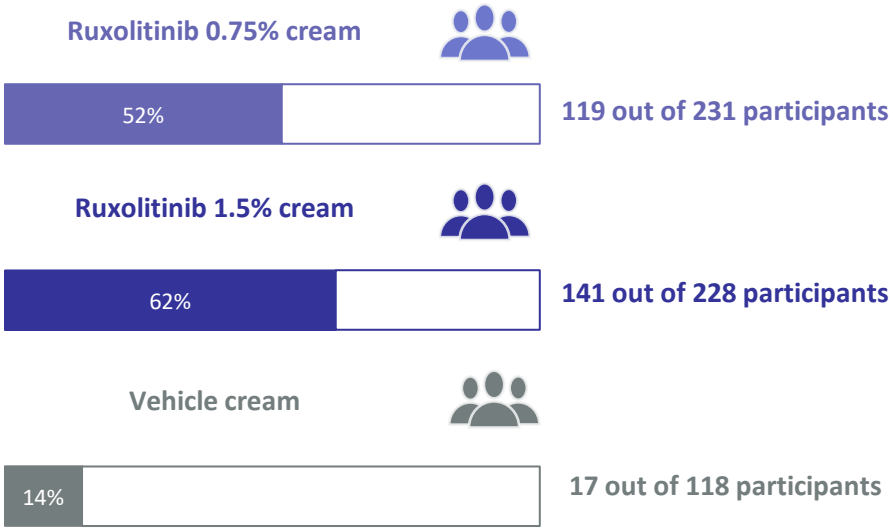
Participants who had clear or almost clear skin after 8 weeks of treatment:



In Europe, the EASI is the standard scale used for measuring the severity of eczema. Using this scale, researchers looked at the number of participants who showed 75% or more improvement in the area affected by eczema and its severity after 8 weeks of twice-a-day treatment. Results of this study after 8 weeks of treatment showed that more participants in

the ruxolitinib cream groups achieved at least a 75% improvement compared to the participants in the vehicle cream group.

Participants who showed 75% or more improvement in eczema extent and severity after 8 weeks of treatment:



7. What side effects did participants have during this study?

A lot of research is needed to know whether a drug causes a side effect. Side effects are unwanted medical events that the study doctor thought might be related to the study drug.

This section is a summary of the serious side effects and most common non-serious side effects that participants experienced during the study.

The websites listed at the end of this summary have more information about the medical events that may or may not be caused by the study drug that happened in this study.

How many participants had serious side effects?

Serious side effects are those that may cause death, disability that lasts for a long time, life-threatening conditions, or hospitalization.

No participants died during this study. During the **VC period**, none of the participants experienced any serious side effects. During the **LTS period**, 1 participant who moved from the vehicle cream to the ruxolitinib 0.75% cream group experienced a serious side effect of

abnormal growth of cells that form the placenta in the uterus, or molar pregnancy (benign hydatidiform mole). None of the other participants experienced any serious side effects.

What were the most common non-serious side effects?

Side effects other than the serious side effects are reported in this section.

VC period

During this period, 3% of participants (8 out of 248) who were given ruxolitinib 0.75% cream, 5% of participants (11 out of 246) who were given ruxolitinib 1.5% cream, and 10% of participants (12 out of 124) who were given vehicle cream reported side effects.

The most common non-serious side effects experienced by more than 1 participant in any group in the VC period:

	Ruxolitinib 0.75% cream (248 participants)	Ruxolitinib 1.5% cream (246 participants)	Vehicle cream (124 participants)
Pain at the application site *(Application site pain)*	**Less than 1%** (2 participants)	**Less than 1%** (2 participants)	**7%** (8 participants)
Itching at the application site *(Application site pruritus)*	**Less than 1%** (2 participants)	**0%** (0 participants)	**3%** (4 participants)

LTS period

During this period, 6% of participants (12 out of 204) who continued with ruxolitinib 0.75% cream and 4% of participants (8 out of 221) who continued with ruxolitinib 1.5% cream experienced side effects. Of those who were on vehicle cream during the **VC period**, 4% of participants (2 out of 53) who moved to ruxolitinib 0.75% cream and 6% of participants (3 out of 52) who moved to ruxolitinib 1.5% cream experienced side effects.

The most common non-serious side effects experienced by more than 1 participant in any group in the LTS period:

	Ruxolitinib 0.75% cream (248 participants)	Ruxolitinib 1.5% cream (246 participants)	Vehicle cream in the VC period	
			Ruxolitinib 0.75% cream (53 participants)	Ruxolitinib 1.5% cream (52 participants)
Increased level of enzyme called alanine aminotransferase in the blood* *(Alanine aminotransferase increased)*	**Less than 1%** (1 participant)	**Less than 1%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)
Itching at the application site *(Application site pruritus)*	**Less than 1%** (1 participant)	**0%** (0 participants)	**2%** (1 participant)	**0%** (0 participants)
Blisters on the skin *(Herpes virus infection)*	**Less than 1%** (1 participant)	**Less than 1%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)
Decreased white blood cells called neutrophils *(Neutropenia)*	**Less than 1%** (1 participant)	**Less than 1%** (1 participant)	**0%** (0 participants)	**2%** (1 participant)
Cold sores *(Oral herpes)*	**Less than 1%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**2%** (1 participant)
*An increase in the level of alanine aminotransferase in the blood may indicate that the liver may be inflamed or injured.				

How many participants stopped the study drug because of side effects?

During the **VC period**, 2 participants who were given vehicle cream stopped the vehicle treatment early because of side effects. The most common side effect that led to participants stopping the vehicle treatment was pain at the application site (application site pain).

During the **LTS period**, none of the participants stopped the study drug because of side effects.

8. How has this study helped patients and researchers?

This study helped patients and researchers learn about the effects and safety of ruxolitinib cream when treating participants with eczema.

The study was completed as planned.

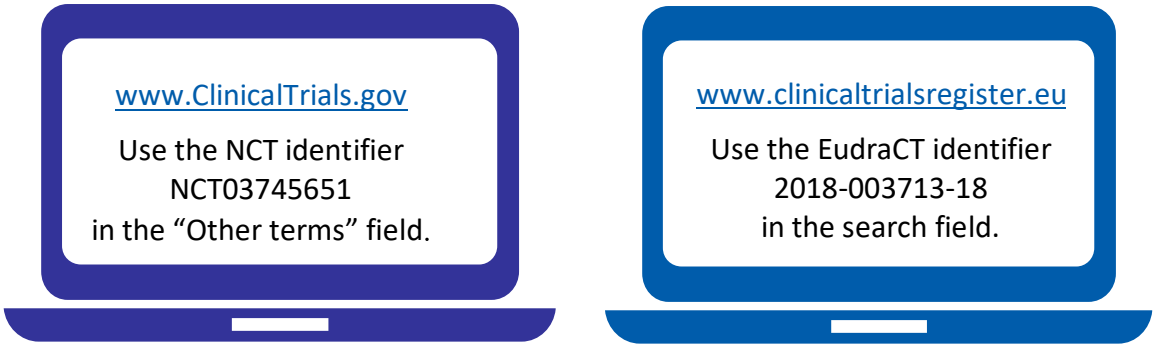
Findings from this study were used to seek approval for using ruxolitinib cream for patients with eczema in the United States and could be used for the same purpose in other countries in the future. These results may also be used to help design other studies with ruxolitinib cream.

9. Are there plans for further studies?

Additional clinical studies with ruxolitinib cream are ongoing.

10. Where can I find more information about this study?

You can find more information about this study on the following websites:



Please remember that the results on these websites may be presented in a different way. If you were a study participant and have questions about the results of this study, please speak with the doctor or staff at your study site.

Full study title: A phase 3, double-blind, randomized, 8-week, vehicle-controlled efficacy and safety study of ruxolitinib cream followed by a long-term safety extension period in adolescents and adults with atopic dermatitis
Protocol number: INCB 18424-304
Sponsor: Incyte Corporation

Sponsor's phone numbers:
+1-855-463-3463 (for United States)
+1-833-309-2759 (for Canada)
+81-120-094-139 (for Japan)

Sponsor's email addresses:
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jpmedinfo@incyte.com (for Japan)
globalmedinfo@incyte.com (outside United States, Canada, and Japan)

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