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SUMMARY CLINICAL STUDY REPORT

PROTOCOL TITLE:	Single-center, Open-label, Non-randomized Clinical Study to Assess the Safety and Efficacy of a Moisturizing Lotion During and After 21 ± 2 Days of Use in Adult Subjects with Atopic Dermatitis.
PROTOCOL NUMBER:	CCSSKA004236 Final Version 1, 27-Apr-202
SITE STUDY NUMBER:	088932-01
NCT Number	NCT05062213
SPONSOR:	JOHNSON & JOHNSON 1020 Manoel Bosco Ribeiro Street 12241-070, São José dos Campos, Brazil
STUDY SITE:	Allergisa Pesquisa Dermato-Cosmética LTDA. 452 Dr. Romeu Tórtima Avenue, 13084-791, Campinas/SP, Brazil +55 19 3789 8610
PRINCIPAL INVESTIGATOR:	Mariane Martins Mosca, Bachelor of Science (Bsc) 452 Dr. Romeu Tórtima Avenue, 13084-791, Campinas/SP, Brazil +55 19 3789 8610 / mariane.mosca@alsglobal.com Note: The Study Physician is medically qualified
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STUDY INITIATION DATE (First Subject First Visit):	01-Nov-2021
STUDY COMPLETION DATE (Last Subject Completed):	04-May-2022
SITE APPROVAL:	See trial master file for final clinical study report and approvals
SPONSOR REVIEW AND APPROVAL:	See trial master file for final clinical study report and approvals

The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

INTRODUCTION	Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by the formation of dermatological lesions accompanied by itching and dry areas. This disease has a prevalence of approximately 4.9% in adults and is mostly accompanied by a personal or family history of another atopy, whether respiratory or AD itself (AOKI V. et al, 2019). AD involves both cutaneous and immunological changes. The most common skin changes include skin barrier dysfunction, characterized by increased trans-epidermal water loss (TEWL), reduced expression of skin proteins, decreased skin hydration due to reduced stratum corneum (SC) water content, and skin microbiome changes (AOKI V. et al, 2019). The latter is the diverse community of microorganisms, including bacteria, that coexist on the surface of the skin. A balanced microbiome is a habitat for thousands to millions of beneficial and harmful bacteria. Therefore, an unbalance of these bacteria can lead to a variety of skin conditions, including acne, eczema, rosacea, aging, and AD itself. The skin microbiome plays an important role in AD. Healthy skin has a balanced microbial barrier and a preserved skin barrier. Atopic skin, on the other hand, has an unbalanced microbiome and an altered skin barrier, allowing vulnerability to irritants that can cause inflammation, rashes, and itching. Often damaged atopic skin is dominated by Staphylococcus aureus (S. aureus) (GRICE EA et al, 2009). Because it has a complex pathogenesis, AD can also present several types of therapeutic management according to its characteristics and severity. Basic therapy involves appropriate skin hygiene and daily use of moisturizers to maintain and restore the integrity of the skin barrier and increase the water content of the SC. In addition, increased skin hydration improves xerosis, may reduce itching, balance the skin microbiome, the AD picture and, consequently, the quality of life of patients (AOKI V. et al, 2019; GALLO and NAKATSUJI, 2011 and STAMATAS and TIERNEY, 2014). Therefore, the development of moisturizing formulations, such as the investigational product (IP) of this study, is essential for this type of pathology. The mechanism of action of IP occurs mainly due to the physicochemical properties of the formulation, through the hydration of the stratum corneum promoted by the combination of ingredients present in the formulation, among which the oily ingredients or emollients and humectants stand out. The hydration mechanism promoted by IP occurs through local chemical reactions and interactions between these formulation ingredients and skin constituents, which assists the skin regeneration and hydration processes by increasing the water content of the stratum corneum; by non-water-soluble ingredients that, when applied to the skin, form a physical barrier that prevents water from leaving the stratum corneum and hence can lead to increased skin hydration and restoration of the protective barrier; and by having a lipid content that can assist in recomposing the integrity of the skin barrier of skin compromised by atopic dermatitis. Therefore, IP presents characteristics of important products to be used by individuals with atopic dermatitis, as part of the basic therapy. Finally, it is important that IPs are safe and effective, especially for the target population. For this, clinical studies involving efficacy and safety testing of products in human beings are conducted. In Brazil, clinical trials in adults are carried out in accordance with the principles of Resolution 466 of 2012, Documents of the Americas, among others, in order to ensure ethics, quality, and Good Clinical Practices (BCP/GCP) (Brazil, 2012 and Pan American Health Organization, 2005).
OBJECTIVE	**Primary Objectives:** To evaluate the IP, JAR Moisturizing Lotion, based on the following parameter in subjects presenting with mild to moderate atopic dermatitis according to the Scoring Atopic Dermatitis Index (SCORAD): • Topical tolerance after 5 ± 1 and 21 ± 2 days of use under normal conditions; **Secondary Objectives:**

<table>
<tr><td></td><td>To evaluate the IP, JAR Moisturizing Lotion, based on the following parameter in subjects presenting with mild to moderate atopic dermatitis according to the SCORAD Index (at the initial study visit):
• IP effect on atopic dermatitis through SCORAD index assessments after 5 ± 1 and 21 ± 2 days of use under normal conditions of use, compared to the subject's baseline condition (T0);
• IP effect on skin hydration through instrumental measurements of electrical capacitance (corneometer) after 5 ± 1 and 21 ± 2 days of IP use under normal conditions, compared to the subject's baseline condition (T0);
• IP effect on the skin barrier through instrumental measurements of trans-epidermal water loss (TEWL) after 5 ± 1 and 21 ± 2 days of IP use under normal conditions, compared to the subject's baseline condition (T0);
• IP effect on the skin microbiome through metagenomics analyzes after 21 ± 2 days of use under normal conditions, compared to the subject's baseline condition (T0);
• Subjective perception of subjects in relation to IP and its subjective effects on parameters related to efficacy for atopic dermatitis and quality of life of the study population through questionnaires applied after 7, 14 and 21 ± 2 days of use under normal conditions;
• IP effect after 7, 14 and 21 ± 2 days of product use under normal conditions, compared to the subject's baseline status (T0) in relation to the most common parameters of atopic dermatitis through the Patient Oriented Eczema Measure (POEM) questionnaire;
• Subjects' experience with the IP through subjective testimonials after 21 ± 2 days of use under normal conditions</td></tr>
<tr><td>STUDY DESIGN</td><td>The study protocol provides the complete study design for the study.</td></tr>
<tr><td>SUBJECT INFORMATION</td><td>The complete eligibility criteria for this study were followed as defined in
the study protocol. Healthy subjects with mild to moderate atopic dermatitis presenting area with atopic dermatitis characteristics dryness/lesion at the initial visit of the study, 18 to 65 years of age who meet the eligibility criteria.</td></tr>
<tr><td>INVESTIGATIONAL STUDY MATERIALS</td><td><table><tr><td>Identification</td><td>Product Type</td></tr><tr><td>Moisturizing lotion</td><td>Investigational Product (IP)</td></tr></table></td></tr>
<tr><td>DOSE AND MODE OF APPLICATION</td><td>Apply twice a day all over the body and face, massaging gently until the entire product is absorbed by the skin. Pay special attention to the driest areas. Reapply as needed. Avoid the eye area when applying the product. In case of accidental contact with eyes, rinse thoroughly. The product is for external use only. Do not ingest. The product is for adult use only.</td></tr>
<tr><td>METHODOLOGY</td><td>The study methodology consisted of evaluations to prove the efficacy and safety of IP in adult subjects with mild to moderate atopic dermatitis, presenting area with atopic dermatitis characteristics dryness/lesion, as described below:
• Assessment of topical tolerance after 5 ± 1 and 21 ± 2 days of use under normal conditions through a scale of dermatological reactions and adverse events;
• Assessment of atopic dermatitis through SCORAD index assessments after 5 ± 1 and 21 ± 2 days of use under normal conditions of use;
• Assessment of skin hydration through instrumental measurements of electrical capacitance (corneometry) after 5 ± 1 and 21 ± 2 days of IP use under normal conditions;
• Skin barrier assessment through instrumental measurements of transepidermal water loss (TEWL) after 5 ± 1 and 21 ± 2 days of IP use under normal conditions;
• Skin microbiome assessment through metagenomic analysis after 21 ± 2 days of use under normal conditions;</td></tr>
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<tr><td></td><td>• Evaluation of the subjective perception of subjects regarding IP and its subjective effects on parameters related to efficacy for atopic dermatitis and quality of life of the study population through questionnaires applied after 7, 14 and 21 ± 2 days of use under normal conditions;
• Assessment of atopic dermatitis after 7, 14 and 21 ± 2 days of product use under normal conditions, using the Patient Oriented Eczema Measure (POEM) questionnaire;
• Evaluation of subjects' experience with the IP through subjective testimonials after 21 ± 2 days of use under normal conditions.</td></tr>
<tr><td>MEASUREMENT AND/OR EVALUATION SCHEDULE</td><td>
<table>
<tr><th>Events</th><th>Visit 1
T0</th><th>Visit 2
T5 ±1</th><th>T7*</th><th>T14*</th><th>VISIT 3
T21 ± 2</th></tr>
<tr><td>Consent Procedure: Signature of the TCLE and of the Consent Term for Image Disclosure</td><td>X</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Eligibility Check (Review of inclusion/exclusion criteria)</td><td>X</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Clinical evaluation of atopic dermatitis using the SCORAD index</td><td>X
(eligibility check and baseline measurement)</td><td>X</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Skin/dermatological acceptability/tolerance evaluation of PI</td><td>X</td><td>X</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Choice of Testing Areas for Skin Microbiome Sampling and Instrumental Analyses and CRF registration</td><td>X</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Skin Microbiome Sampling</td><td>X</td><td>-</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Hydration measurements with Corneometer® in injured and non-injured area</td><td>X</td><td>X</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Measurements of skin barrier integrity evaluation with Tewameter® in injured and non-injured area</td><td>X</td><td>X</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Standardized images of areas with and without dryness of AD</td><td>X</td><td>X</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Distribution of study diary and IP, as well as instructions for use</td><td>X</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Distribution of Questionnaires to be answered at home</td><td>-</td><td>X</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>POEM Questionnaire (Patient Oriented Eczema Measure)</td><td>X</td><td>-</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>JAR Moisturizing Lotion Perception/Quality of Life Questionnaires</td><td>X</td><td>-</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>Return of perception questionnaires answered at home</td><td>-</td><td>-</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Return of IP and Diaries and accounting</td><td>-</td><td>-</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Verification of compliance with the study: weighing the IP units and reviewing the diaries</td><td>-</td><td>X</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>AE assessment</td><td colspan="5">It will take place for the entire duration of the study</td></tr>
<tr><td>Concomitant Medications Verification</td><td>X</td><td>X</td><td>-</td><td>-</td><td>X</td></tr>
<tr><td>Testimony of the subjects</td><td>-</td><td>-</td><td>-</td><td>-</td><td>X</td></tr>
</table>
*Note: There are no visits in T7 and T14. The questionnaires to be answered on these days will be delivered to the subjects and answered by them at home.
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<tr><td>INSTITUTIONAL REVIEW BOARD (IRB)</td><td>This study was reviewed and approved by the following IRB/IEC:
- Investiga – Institutos de Pesquisa
- Approval date: 14-Mar-2022.</td></tr>
<tr><td>SAFETY AND ADVERSE EVENTS</td><td>All Adverse Events (AEs/SAEs) were collected regardless of causal relationship to the subject’s participation in the study. The information was collected/reported within the reporting timelines specified in the protocol.
The conclusion on the IP’s safety for the study population was issued by the Study Physician based on the study safety results presented in this summary clinical study report.</td></tr>
<tr><td>MONITORING, QUALITY CONTROL, AND QUALITY ASSURANCE</td><td>The study monitoring was conducted as per the Sponsor´s requirements. The Study Site was/is subject to review by the IRB, to quality assurance audits performed by the Sponsor, and/or to inspection by appropriate regulatory authorities.</td></tr>
<tr><td>OVERALL CONCLUSIONS</td><td>Dermatological Tolerance Assessment
The IP was considered safe under the evaluated conditions.</td></tr>
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Skin Hydration Assessment
A significant improvement for skin hydration was observed for areas with and without Atopic Dermatitis characteristics dryness/lesion after 5 and 21 days of product use.

Skin Barrier Assessment
While the reduction for transepidermal water loss was not significant, it was trending towards a less compromised state.

Clinical Evaluation of Atopic Dermatitis by SCORAD (Scoring Atopic Dermatitis)
A significant reduction for severity of the lesion, subjective symptoms and SCORAD was observed after 5 and 21 days of product use and after 21 days of product use compared to 5 days of use. A significant reduction for total surface of lesion was observed after 21 days of product use and after 21 days of product use compared to 5 days of use. A significant reduction of Erythema, Edema and Lichenification was observed after 5 days of product use and a significant reduction of Erythema, Edema, Exudation/crusts, Lichenification and Dry skin (xerosis) was observed after 21 days of product use. A significant reduction of Pruritus, Sleep loss and Objective SCORAD was observed after 5 and 21 days of product use and after 21 days of product use compared to 5 days of use.

POEM (Patient Oriented Eczema Measure for Adults)
A significant reduction in the severity of atopic dermatitis/eczema was observed after 7, 14 and 21 days of product use and after 14 and 21 days of product use compared to 7 days of product use.

Skin Microbiome
The species *S. aureus* was twice more present in the microbiome of the study subjects initially at baseline than after 21 days of investigational product use, in both areas with and without AD Characteristics dryness/lesion, indicating that the use of the product for 21 days can reduce the population of this species that is correlated with AD, suggesting an improvement of the subject's skin microbiome. There was no significant change in the population of *Cutibacterium acnespecies*, the main species present in human skin, in the microbiome of the study subjects. A maintenance of alpha-diversity (Shannon's Index) was observed after 21 days of product use for both areas with and without Atopic Dermatitis Characteristics dryness/lesion. It means there was no significant change in the microbiome composition of the study subjects in the areas with and without Atopic Dermatitis Characteristics dryness/lesion after 21 days of product use, indicating that the product preserved the bacterial diversity of the subjects' microbiome. Regarding Beta-diversity, which measures the similarity or dissimilarity of two communities, the principal coordinate analysis showed that there is a significant difference between the times T0 and T21 (p=0.007) and between the areas with and without AD Characteristics dryness/lesion (p=0.02).

Self-Assessments

After 7 Days of use

Statement	% agreement
Reduces flaking from the 1st application	80%
Formula with creamy texture	90%
It is easy to spread	93%
Better night' sleep from the 1st application	93%
Gentle application to the skin	87%

Texture suitable for day-to-day use	87%

After 21 Days of use

Statement	% agreement
I feel my skin more beautiful	93%
Relieves AD uncomfortable using only 1 IP	97%
Reconstructed skin sensation	90%
I see my skin looking healthier day by day	97%
Improved my quality of life	100%
Sensation of relief for the skin	87%
Relieves itching	93%
Reduces flaking	97%
Made using more pleasant and easier	90%
Relieves redness	97%

Questionnaire related to Quality of Life

Before Product Use

How much have the symptoms and discomfort of AD negatively impacted the following questions?	% Moderately affected+Affected very much
Your social interactions with people inside or outside your house?	80.0%
Your social interactions in public places like walks, leisure, shopping, etc.?	80.0%
Your mood/irritability?	60.0%
Your self-esteem, embarrassment?	60.0%

After Product Use

How much has using the JAR Moisturizing Lotion helped improve the questions below?	% Helped a lot+Helped moderately
Your social interactions with people inside or outside your house?	93.3%
Your mood/irritability?	100.0%
Your self-esteem, embarrassment?	93.3%

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