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A clinical research study in adults with chronic hand eczema, atopic dermatitis or vitiligo, to evaluate the safety and tolerability of a topically applied product that consists of ceramic sub-millimeter scale particles that are intended to create microscopic pores in the skin

Submission date
09/12/2024

Recruitment status
Recruiting

Registration date
14/01/2025

Overall study status
Ongoing

Last Edited
06/06/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Drug delivery to the skin is highly constrained by the stratum corneum (outer layer of the skin). STAR particles (a medical device) are sub-millimeter scale particles made of biocompatible materials that can be incorporated into a topical formulation. Rubbing the STAR particles on the skin creates transient micro-size pores to allow delivery of topically applied drug products to the inner layers of the skin. In this way, STAR particles can be used to treat skin conditions. This study aims to assess the safety and tolerability of STAR particles in patients with atopic dermatitis (AD), chronic hand eczema (CHE), or vitiligo. This study does not include the use of any active drug ingredient.

Who can participate?
Adult patients between the ages of 18 and 55 years old with AD, CHE, or vitiligo.

What does the study involve?
Study products, [STAR particles formulation or vehicle (formulation without STAR particles)], will be applied to identified application areas each of 3 x 3 cm. In vitiligo subjects, each study product will be applied daily for eight consecutive days. In AD and CHE subjects, each study product will be applied three times a week for a total of four applications. The study products will be applied with the index and middle fingers using pressure. Approximately 90 mg (10mg /cm2) of product will be applied in each area for 30 seconds.

What are the possible benefits and risks of participating?
You should not expect any improvement in your skin condition from participating in this study since no active drug is included. The information from this study may help our understanding of

the safety of STAR particles in patients with a similar skin condition to yours. When the STAR particles are applied to the skin, the possible risks include local skin reactions at the site of STAR particle application, including redness, swelling, bleeding, and/or discomfort, or a worsening of your skin condition. Previous human research with STAR particles shows that systemic reactions are unlikely to occur. Additionally, the STAR particles did not remain in the skin in prior trials.

Where is the study run from?
Center for Clinical Pharmacology Applied to Dermatology (CPCAD), France.

When is the study starting and how long is it expected to run for?
May 2024 to December 2025

Who is funding the study?
Aldena Therapeutics

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
22.02.STAR / CPC-3644

Study information

Scientific Title
Safety and tolerability of STAR particles on chronic hand eczema, atopic dermatitis and vitiligo patients: a pilot study

Study objectives
Topical application of STAR particles to the skin is safe and well tolerated.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/09/2024, National Agency for the Safety of Medicines and Health Products (ANSM) (143/147, boulevard Anatole France, SAINT-DENIS, 93285, France; +33.(0)1.55.87.30.00; EC.DM-COS@ansm.sante.fr), ref: 2023-A01897-38

Study design

Open-label randomized vehicle-controlled intraindividual pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Laboratory

Study type(s)
Safety

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Tolerability of topically applied STAR particles will be assessed in subjects with atopic dermatitis (AD), chronic hand eczema (CHE), or vitiligo

Interventions
STAR particles are sub-millimeter medical devices made of biocompatible materials that, when rubbed on the skin, create transient micro-pores, allowing the delivery of topical drugs and potentially enabling the treatment of skin conditions. This study aims to assess the safety and tolerability of STAR particles in patients with atopic dermatitis (AD), chronic hand eczema (CHE), or vitiligo. The study products are the STAR particles gel formulation and vehicle (gel formulation without STAR particles), without any active ingredient.

Each participant will have application areas of 3x3 cm in non-lesional and lesional skin to receive both study products (intraindividual design).

In vitiligo subjects, each study product will be applied daily for eight consecutive days. In AD and CHE subjects, each study product will be applied on Days 1, 3, 5, and 8, for a total of four applications.

Overall, application on Days 1, 2, and 8 will be performed at the study centre by trained personnel. Application on Day 3 will be performed by the subject at the study centre under the supervision of the trained personnel and application from Day 4 to Day 7 will be performed by the subject himself/herself at home when applicable.

The study products will be applied by rubbing in a circular direction with the index and middle fingers using pressure. Approximately 90mg (10mg/cm2) of product will be applied in each area for 30 seconds. Five minutes after the end of the product application, the STAR particles will be removed with a dry tissue or dry gauze pad.

A demonstration of the adequate pressure to be applied by the investigator and the subjects will be carried out using an appropriate scale. An Instruction For Use (IFU) will be provided to the investigator and the subjects. Subjects will be educated and guided on area delimitation and application methods by the study staff and the IFU.

Intervention Type
Device

Pharmaceutical study type(s)
Tolerability

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
STAR particles

Primary outcome measure
Safety and tolerability will be assessed via the following outcome variables over 8 days followed by a 5-day follow-up period:
1. The incidence and severity of adverse events, serious adverse events, and application site reactions measured using Case Report Forms (CRF)
2. The incidence and severity of adverse device effects, serious adverse device effects measured using Case Report Forms (CRF)
3. Recording vital signs, including measurement of systolic and diastolic blood pressure and pulse rate in the sitting position, measured using standard methods
4. Performing physical examinations evaluating the skin (other than the study disease), lungs, abdomen, eyes/ears/nose/throat, neurological function, musculoskeletal system, lymph nodes, and cardiovascular system

Secondary outcome measures
1. Assess the skin puncture measured using Gentian Violet (GV) staining on Day 1 and Day 8
2. Monitor skin permeability measured using the Trans-Epidermal Water Loss (TEWL) test before and after product application on Day 1 and Day 8
3. Erythema and pigmentation changes measured using a clinical assessment on Day 1, Day 2 (for vitiligo patients only), Day 3, and Day 8
4. Acceptability of the product application measured using a patient questionnaire on Day 1 and Day 8
5. Usability feedback assessment measured using a usability questionnaire on Day 8

Exploratory outcome measures:
1. Depth of transepidermal poration or STAR skin embedment measured using Optical Coherence Tomography (OCT) imaging before and after product application
2. Skin colonization (Staphylococcus aureus and total aerobic bacterial count) measured using microbial counting and standard laboratory techniques on Day 1 and Day 8 skin swabs

Overall study start date
01/05/2024

Completion date
30/12/2025

Eligibility

Key inclusion criteria

1. Subject with a clinically confirmed diagnosis of only one of the following conditions: chronic hand eczema (CHE), atopic dermatitis (AD) or non-segmental vitiligo
2. All subjects should have two (2) symmetrical areas of at least 3 x 3 cm without lesions (non-lesional skin) on the anterior forearm
3. For vitiligo: Subject has clinical diagnosis of stable non-segmental vitiligo, defined as no new depigmented lesions or progression of pre-existing depigmented lesions, and absence of Koebner phenomenon within approximately the last 12 months (information obtained from medical chart or subject's physician, or directly from subject)
4. For vitiligo: subject has non-facial vitiligo that can accommodate two application areas on non-active lesional skin of 3 x 3 cm in easy-to-treat areas, including but not limited to the trunk, arms, or thighs. They should not be located on the hands, wrists, feet, elbows, scalp, genitals, or intertriginous areas. If on the trunk, the application areas should be ≥ 3 cm apart
5. For AD: subject has two application areas on lesional skin of 3 x 3 cm on symmetrical body areas and excluding face, scalp, genitals, axillae, groin, and feet. The difference in the Total Sign Score between both lesions should not exceed 1
6. For CHE: subject has four application areas of 3 x 3 cm (on the palm and dorsum of both hands) with symmetrical lesion, including: both palms and dorsum of both hands are affected; both palms are affected, and both dorsum are not affected; both dorsum are affected, and both palms are not affected
7. Female subjects of childbearing potential must use a reliable method of contraception and agree not to change it during the study
8. Subject able to comprehend the full nature and the purpose of the investigation, including possible risks and side effects, and subjects able to cooperate with the Investigator and to comply with the requirements of the entire investigation (including ability to attend all the planned investigation visits according to the time limits), based on Investigator's judgement
9. Subject affiliated to a health social security system (according to French Law)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
10 subjects with CHE, 10 subjects with AD, 10 subjects with non-segmental vitiligo

Key exclusion criteria
1. Female who is pregnant or breastfeeding or who plans to become pregnant during the study
2. Subject with known allergy to any materials and/or ingredients of the study products
3. Subject with known allergy to Gentian Violet stain
4. Known triggers for CHE (allergic or irritant) cannot be avoided during the course of the study
5. Subject with any other inflammatory skin disease or evidence of other skin conditions on the

treatment areas
6. Subject with physical urticaria (including dermatographism) or angioedema
7. Subject with any clinically significant cutaneous or systemic infection including primary viral infections of the skin (e.g. herpes, HIV, hepatitis B)
8. Subject has used systemic treatments that could affect vitiligo, CHE, or AD within 8 weeks prior to the pretreatment period or within 5 half-lives, whichever is longer
9. Subject with an immunosuppressive disease
10. Subject who has any other clinically significant medical condition or physical/vital signs abnormality that would, in the opinion of the investigator, put the subject at undue risk or interfere with the interpretation of investigation results
11. Subject who has used topical skin care on the treatment areas within 24h prior to Day 1 /Baseline
12. Subject who has used within one week prior to the study topical dermatological drug therapy on the treatment areas. Topical treatment of vitiligo, CHE, and AD will be allowed in non-application areas
13. Subject who has used systemic treatments such as analgesics (including paracetamol) within 24h prior to Day 1/Baseline or antihistamines within one week prior to Day 1/Baseline
14. Subject impossible to be contacted in case of emergency
15. Subject currently participating or having participated in another clinical trial/investigation during the month preceding inclusion
16. Subject who had been deprived of their freedom by administrative or legal decision or is under care of guardian or legal guardianship or subject hospitalized in a medical or social establishment for any reason
17. Subject having received 6000 euros indemnities for participation in clinical trials /investigations in the 12 previous months, including participation in the present study (according to French Law)

Date of first enrolment
09/12/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
France

Study participating centre
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Sponsor information

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Aldena Therapeutics

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Aldena Therapeutics

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date