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A patch test study of STS01 in healthy volunteers

Submission date
11/05/2022

Recruitment status
No longer recruiting

Registration date
08/08/2022

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In order to address the factors associated with poor tolerability and compliance with the administration of current preparations, the investigational medicinal product (IMP) will be a controlled release, cream-based, formulation STS01. The silicon atoms are 'activated' (electrically charged) to enable a controllable 'honeycomb' pore structure as a drug delivery mechanism with the potential to offer enhanced targeting and release characteristics. The main aim of this study is to look at whether a new controlled release formulation of STS01 has a beneficial effect on the skin irritation and skin staining potential that is seen with normal cream.

Who can participate?
Healthy volunteers aged 18 – 70 years

What does the study involve?
The study will comprise an initial open, prolonged exposure study (safety phase) to inform safety for the repeated application study (repeated phase). The safety phase is designed to determine the skin irritancy of each of the four topical formulations in healthy volunteer subjects, compared to the Base Formulation (with no dithranol) and E45 Dermatological Cream. The study will involve a progressive patch test with an increasing duration of exposure of up to 8 hours with follow-up assessments at 24, 48 and 72 hours. This approach is designed to minimise the exposure risk for the participants. Such an approach has been used previously to determine the irritancy of chemicals classified as irritants with no risk to participants. The repeat phase will be a double-blind, randomised study of the same set of creams, which will be applied to the lower back area of the participants. The creams will be applied to the test sites for periods of 1 hour on seven consecutive days with assessments on Days 1-13 and Day 16. Any clinical signs of cutaneous irritation (or any other clinical signs) will be recorded.

What are the possible benefits and risks of participating?
This approach is designed to minimise the exposure risk for the participants. Such an approach has been used previously to determine the irritancy of chemicals classified as irritants with no risk to participants. Possible side effects from using other dithranol products include skin irritation and staining. The dithranol/ProSilic® cream formulation controls the drug release from the cream preparation and reduces this risk. Participants with an allergy likely to interfere with

the study are excluded. Participants will need to attend the Phase I unit clinic up to a maximum of four occasions. Participants who participated in the safety phase and had dithranol formulations applied to the skin may not participate in the repeated phase.

Where is the study run from?
Soterios Ltd (UK)

When is the study starting and how long is it expected to run for?
May 2022 to December 2022

Who is funding the study?
Soterios Ltd (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
2022-001272-34

IRAS number
1005742

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
AN3476/SOT03, IRAS 1005742

Study information

Scientific Title
A repeat open application patch test (ROAT) using a new controlled release formulation of STS01 cream in healthy volunteer subjects, preceded by a preliminary safety phase

Study objectives
The primary objective is to investigate the irritancy and staining potential with a new controlled release formulation of STS01. The study will comprise an initial open, prolonged exposure study (“safety phase”) to inform safety for the repeated application study (“repeated phase”).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/07/2022, Wales REC 1 (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2920785738; wales.REC1@wales.mhs.uk), ref: 22/WA/0151

Study design
Double-blind randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy volunteer study - the treatment is for alopecia areata

Interventions
Participants are randomised to a patch test of STS01 topical cream in strengths of 0.0%, 0.25%, 0.5%, 1% and 2% w/w or a control treatment (E45 Dermatological Cream); applied once.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
STS01

Primary outcome measure
Assessment of test product contact with the skin using appropriate ranking scales, chromameter measurements and thermometry measurements. Staining of the application area will also be assessed by imaging (camera or TiVi Imaging System). Cream application sites will be assessed after a minimum of 10 minutes and a maximum of 30 minutes to allow any reactions due to the removal of the tape and test chamber to subside. The test chambers will be removed and assessed at 1, 2, 4 and 8 hours.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
09/05/2022

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Subjects who are in the age range 18 – 70 years
2. Subjects with no significant concurrent illnesses or skin disease
3. Subjects who have signed the consent form after the nature of the study has been fully explained

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
60

Total final enrolment
59

Key exclusion criteria
1. Pregnant or breastfeeding or lactating females or females who have given birth in the last 6 weeks
2. Subjects with a diagnosis of psoriasis, even if disease is not currently active
3. Subjects who participated in the safety phase and had dithranol formulations applied to the skin may not participate in the repeated phase
4. Subjects with atopy, self-diagnosed sensitive skin, or other dermatoses
5. Subjects who take any systemic or topical medication likely to interfere with the study e.g., anti-inflammatory drugs such as systemic steroids
6. Subjects who have taken part in a Health Research Authority or MHRA regulated clinical trial (e.g., at a hospital or Phase I unit) within the previous 8 weeks
7. Subjects who have taken part in a study involving the test site during the previous 4 weeks
8. Subjects with a recent history (previous 12 months) of significant skin disease requiring medical intervention, e.g., Dermatology outpatient appointment
9. Subjects with an allergy likely to interfere with the study
10. Subjects with a recent history of/or evidence of alcohol, substance or drug abuse

Date of first enrolment
09/06/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
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Sponsor information

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Soterios Ltd

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Submission to regulatory authorities

Intention to publish date
30/12/2023

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Basic results	version 1	23/12/2024	17/01/2025	No	No