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STS-01 for the treatment of alopecia areata

Submission date	Recruitment status	[X] Prospectively registered
19/03/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/12/2024	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
STS-01 is being developed to address the need for an effective, safe and convenient non-steroidal topical treatment for alopecia areata (patchy hair loss). The product builds on a mechanism with a well-established safety profile in dermatology, and existing evidence of its effectiveness in this condition through targeting key relevant cytokines. STS-01 has been modified to maximise the effectiveness of this mechanism and offer a cosmetically elegant topical cream. The study aims to assess the effectiveness, safety and dose-response characteristics of STS-01 for the treatment of alopecia areata

Who can participate?
Patients aged over 18 years with active patchy alopecia areata who are not currently using any other hair loss medication

What does the study involve?
Participants are randomly allocated to be treated with either STS-01 or a placebo (dummy) drug. The medication is applied to the affected area daily for 6 months. Improvement is monitored at 2 monthly intervals (0, 2, 4, 6 months) by photography, a questionnaire is completed and a blood sample is taken for the assessment of inflammation.

What are the possible benefits and risks of participating?
The patient can simply apply the medication without complicated instructions for use and removal. The patient should see hair regrowth start in 4-6 weeks. The old standard STS-01 preparation was sometimes known to cause staining and irritation and although this is unlikely to happen with the new formulation it may occur in some individuals.

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

When is the study starting and how long is it expected to run for?
January 2019 to June 2024

Who is funding the study?
Soterios Ltd (UK)

Who is the main contact?
Tony Brown
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Study website
https://soteriospharma.com/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2021-004145-20

IRAS number
304441

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SOT01, IRAS 304441, CPMS 50463

Study information

Scientific Title
A double-blind, multi-site, placebo-controlled, parallel-group design to assess the efficacy, safety and dose-response characterisation of STS-01 for the treatment of alopecia areata

Acronym
SOT01

Study objectives
STS01 improves hair growth over placebo controls in alopecia areata (AA) patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2021, London - South East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8085; londonsoutheast.rec@hra.nhs.uk), ref: 21/LO/0851

Study design
Double-blind multi-site randomized placebo-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Alopecia areata

Interventions
Participants are block randomised to be treated with 0.25%, 0.5%, 1.0%, 2% STS-01 or a matching placebo control topically once daily for 6 months with a 2-month follow up.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
STS-01

Primary outcome measure
Alopecia areata severity measured using the Severity of Alopecia Tool (SALT) at 0, 2, 4 and 6 months with a 2-month follow up

Secondary outcome measures
Measured at 0, 2, 4 and 6 months with a 2-month follow up
1. Regrowth area measured by graphical measuring of the size of the patch
2. AA quality of life measured using Subject Alopecia Areata Symptom Impact Scale (AASIS) and Alopecia Areata Quality of Life Index (AAQLI) 0-25
3. Global assessment using the Clinical Global Impression (CGI) score
4. Cytokines measured using assay of interleukins

Overall study start date
01/01/2019

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Alopecia areata (<50% SALT score)
2. Not currently receiving treatment for hair loss

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
Severe alopecia areata (totalis/universalis)

Date of first enrolment
23/03/2022

Date of final enrolment
23/09/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Salford Royal Hospital
Stott Lane Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
St Lukes Hospital
Little Horton Lane
Bradford
United Kingdom
BD5 0NA

Study participating centre
Royal Alexandra Children's Hospital
Eastern Road
Brighton

United Kingdom
BN2 5BE

Study participating centre
Queen Margaret Hospital
Whitefield Road
Dunfermline
United Kingdom
KY12 0SU

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Queen Anne Street Medical Centre Limited
18-22 Queen Anne Street
London
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W1G 8HU

Study participating centre
Queen Elizabeth University Hospital
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G51 4TF

Study participating centre
Norfolk and Norwich University Hospital
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NR4 7UY

Study participating centre

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Soterios Ltd

Results and Publications

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

Intention to publish date
31/12/2025

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	11/10/2021	21/03/2022	No	Yes
HRA research summary			28/06/2023	No	No