

STS-01 for the treatment of alopecia areata

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| Submission date 19/03/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 21/03/2022 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 04/12/2024 | Condition category Skin and Connective Tissue Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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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Contact information

Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-004145-20

Integrated Research Application System (IRAS)
304441

Central Portfolio Management System (CPMS)
50463

Protocol serial number
SOT01

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Scotland

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
United Kingdom
W1G 8HU

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road Walsgrave
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
Soterios Ltd

Funder(s)

Funder type

Industry

Funder Name

Soterios Ltd

Results and Publications

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 |
| Participant information sheet | version 1 | 11/10/2021 | 21/03/2022 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |