ISRCTN59816814 https://doi.org/10.1186/ISRCTN59816814

A study to assess the safety and efficacy of aurase wound gel (24U/mL) in treating venous leg ulcers

Submission date
16/10/2024

Recruitment status
No longer recruiting

Registration date
22/11/2024

Overall study status
Completed

Last Edited
22/05/2026

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
The purpose of this research study is to learn about a new medication called Aurase Wound Gel and to assess how safe and effective it is in treating a type of slow or non-healing wound called Venous Leg Ulcers (VLUs). VLUs are difficult to heal and often require special care. One important step in the healing process is removing unhealthy tissue from the wound, known as wound debridement. This study will investigate whether Aurase Wound Gel can safely and effectively help clean and heal these ulcers within a 3-week treatment period. This is the second clinical trial for Aurase Wound Gel. In the first study, researchers used lower concentrations and saw good results with no safety concerns. This time, they will use a stronger concentration (24 U /ml) but apply less gel (2 ml for every 10 cm^2 of wound area). This ensures participants get a similar daily dose as before. The focus will be on how well the new gel cleans the wound and promotes healing, while monitoring for any side effects.

Who can participate?
Adults over the age of 18 years old who have a VLU that requires assistance in removing unhealthy tissue to help it heal.

What does the study involve?
Participants are involved in this study for about 6 weeks, during which they visit the research center 11 times. The study begins with a 2-week screening period, providing only standard wound care. After this, eligible participants are randomly assigned to one of two groups:
Group 1: Standard Care, which includes a commonly used gel and additional treatments for healing.
Group 2: Aurase Wound Gel (24 U/ml) along with additional dressings.
The treatment is reapplied every 2 to 3 days during the 3-week treatment phase. At each visit, the care team cleans the wound, takes photographs, assesses healing progress, and applies new dressings. The study team also monitors for side effects and inquires about participants' overall health and any new medications.

What are the possible benefits and risks of participating?
By participating in this study, individuals may benefit from receiving new treatments for their wounds, potentially leading to better healing outcomes. While the Aurase Wound Gel is still being tested and is not yet approved, participants will receive the best available standard care during the study. Their wounds may become cleaner, less painful, and may heal faster. However, as with any medical treatment, there may be risks involved, including possible side effects from the gel. The study team will closely monitor participants to manage any adverse effects.

Where is the study run from?
The CLEANVLU2 study is being run by Home Wound Care UK

When is the study starting and how long is it expected to run for?
October 2024 to February 2026

Who is funding the study?
SolasCure Ltd (UK)

Who is the main contact?
SolasCure Ltd, clinicaltrials@solascure.com

Contact information

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1010587

Protocol serial number
SC_VLU_003

Study information

Scientific Title
A pilot, randomised, parallel group, study to assess the safety and debridement efficacy of Aurase Wound Gel (AWG) 24 U/mL compared to Standard of Care in patients with sloughy Venous Leg Ulcers

Study objectives
The 24 U/ml concentration of Aurase Wound Gel will exhibit a systemic and local adverse event profile that is comparable to or lower than the expected profile for similar wound care products, while also achieving significantly greater clinically meaningful wound debridement compared to standard care after 1, 2, and 3 weeks of treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/11/2024, South West - Central Bristol Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048194; centralbristol.rec@hra.nhs.uk), ref: 24/SW/0127

Primary study design
Interventional

Study design
Single-center interventional open-blinded randomized-controlled parallel-group trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Chronic (non-healing) ulcers of the lower leg

Interventions
Participants are randomized into one of two arms in a 1:2 ratio as follows:

Group 1: Standard of Care [comprising ActivHeal + secondary dressing + compression bandaging] (n = 10), applied three times weekly at the time of routine dressing change, for 3 weeks.

Group 2: Aurase Wound Gel [24 U/ml] + secondary dressing + compression bandaging (n = 20), applied three times weekly at a volume of 0.2 ml/cm2 at the time of routine dressing change for 3 weeks.

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
Aurase Wound Gel [Tarumase]

Primary outcome(s)
1. Frequency and severity of adverse events measured using standardized adverse event reporting forms over 4 weeks
2. Frequency and severity of reference wound-related local adverse events (AEs) measured at each visit using standardized forms, focusing on pain, redness, swelling, and exudate (incidence of treatment-emergent AEs and serious AEs [SAEs]) over the period of the study

Key secondary outcome(s)
Debridement efficacy will be measured by assessing:
1. Proportion of patients achieving “complete debridement” measured by clinical assessor upon assessment of wound at 3, 6, and 9 applications
2. Mean/median reduction in slough and eschar content measured using the percentage of wound surface area, at 1, 2, and 3 weeks (Change in surface area of devitalised tissue compared to baseline)
3. Time to achieve complete debridement measured using data recorded for each patient (in days)
4. Extent of recurrence of slough measured using data recording treatment discontinuation (Percentage of wound area)

Healing potential will be measured by assessing:
5. Proportion of granulation tissue measured using the percentage of wound surface area at 1, 2, 3, and 4 weeks
6. Linear wound healing rates measured using recorded data to calculate over 1, 2, 3, and 4 weeks, recorded in mm/day
7. Mean/median surface area reduction measured using recorded data over 1, 2, 3, and 4 weeks, recorded in cm2 and as a percentage
8. Linear healing rates measured using recorded data to compare between the 2-week run-in period and the first/last 2 weeks of treatment, recorded in mm/day.
9. Mean surface area reduction measured using recorded data to compare between the 2-week run-in period and the first/last 2 weeks of treatment. (Percentage of wound surface area)
10. Change in study wound pain burden from baseline measured using a Numerical Rating Scale (NRS) measured at each visit
11. Wound QoL measured using the Forgotten Wound Score (QoL) at visit 1, 2 and 11

Completion date
18/02/2026

Eligibility

Key inclusion criteria

1. Male or female participants aged 18 years and older at screening who are willing and able to attend and comply with all study visits and study-related activities
2. Provide a signed and dated written informed consent
3. Presence of ≥50% slough or devitalized tissue within the reference ulcer and suitable for debridement therapy
4. Participants with at least one defined VLU suitable for treatment that is no smaller than 2 cm2 and no larger than 50 cm2 and is confirmed as venous in origin by clinical assessments, by Ankle Brachial Pressure Index (ABPI) ≥0.8 and/or toe systolic BP pressure > 70mm Hg. Participants with more than one VLU on the target leg can be included, provided other ulcers are at least 1 cm away from the reference ulcer identified for treatment. Selection of the reference ulcer will be at the investigator's discretion, provided it meets all other inclusion/exclusion criteria.
5. Confirmed, clinically diagnosed VLU (ulceration of the lower limb, with no other mechanistic explanation and which has persisted for 6 weeks or more) but which has been present for ≤2 years, defined by patient reporting or clinical records

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
14

Key exclusion criteria
1. Reduction in the wound area of ≥40% within the 2-week screening period, when administered standard of care [moist wound healing dressing + compression bandaging] only
2. Participants who have reported poorly controlled diabetes within 3 months of the screening period
3. Participants with amputation above a trans metatarsal amputation (TMA) in the target leg
4. Reference ulcer has exposed tendons, ligaments, muscle, or bone
5. Reference ulcer [at end of screening] with high levels of exudate, which in the opinion of the investigator, would render the proposed trial management protocol unsuitable
6. Reference ulcer has an active infection at screening determined by the investigator using clinical assessment
7. Active osteomyelitis, cellulitis or gangrene in either leg
8. Participants with current active malignancy [other than basal cell carcinoma] requiring active immune or chemotherapy treatment

9. Planned vascular surgery, angioplasty, or thrombolysis procedures within the study period, or 4 weeks before screening
10. Prior skin graft, negative pressure therapy, ultrasound therapy, systemic or cutaneously applied growth factor, other enzymatic debriding agents (e.g. Collagenase, Nexobrid) or live maggot therapy applied to the reference ulcer within 2 weeks before screening
11. Currently enrolled or has been enrolled in the last 30 days in another investigational device or drug study
12. Known allergy or hypersensitivity to any component of the investigational product, medication or surgical dressings to be used in the study
13. Participants who lack the capacity to provide informed consent
14. Any patient which the investigator otherwise considers unsuitable for entry into the study, by reason of acute or chronic mental or physical condition that may interfere with the collection of safety and/or efficacy data
15. Pregnant or breastfeeding women

Date of first enrolment
06/01/2025

Date of final enrolment
14/11/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Leicestershire Medical Group
Smeeton Road Kibworth Beauchamp
Leicester
England
LE8 0LG

Sponsor information

Organisation
SolasCure Ltd

Funder(s)

Funder type
Industry

Funder Name
SolasCure Limited

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from David Fairlamb, Chief Development Officer, SolasCure. davidfairlamb@solascure.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/05/2026	21/05/2026	No	No
Dataset			22/05/2026	No	No
Plain English results			21/05/2026	No	Yes
Protocol file	version 5.0	03/09/2025	21/05/2026	No	No
Statistical Analysis Plan	version 2.0	31/12/2025	21/05/2026	No	No