

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

<b>Submission date</b> 16/10/2024	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/11/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/05/2025	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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<sup>2</sup> 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 Aurse 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 December 2025

Who is funding the study?

SolasCure Ltd (UK)

Who is the main contact?

SolasCure Ltd, [clinicaltrials@solascure.com](mailto:clinicaltrials@solascure.com)

## Contact information

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Public, Scientific

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

1010587

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

## Study design

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

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Community, GP practice

## Study type(s)

Safety, Efficacy

## **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**

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/cm<sup>2</sup> at the time of routine dressing change for 3 weeks.

## **Intervention Type**

Biological/Vaccine

## **Pharmaceutical study type(s)**

Pharmacodynamic, Dose response, Therapy

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

Aurase Wound Gel [Tarumase]

## **Primary outcome measure**

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

## **Secondary outcome measures**

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 cm<sup>2</sup> 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

**Overall study start date**

11/10/2024

**Completion date**

31/12/2025

## 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 cm<sup>2</sup> and no larger than 50 cm<sup>2</sup> 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30

## **Key exclusion criteria**

1. Reduction in the wound area of  $\geq 40\%$  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**

31/10/2025

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**South Leicestershire Medical Group**

Smeeton Road Kibworth Beauchamp

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SolasCure Ltd

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## Sponsor type

Industry

# Funder(s)

## Funder type

Industry

## Funder Name

SolasCure Limited

# Results and Publications

## Publication and dissemination plan

1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Submission to regulatory authorities
6. Anonymised data via the clinical study report will be made available, as will public summaries of the data on public websites such as ISRCTN.

## Intention to publish date

01/07/2026

## 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