STATISTICAL ANALYSIS PLAN

Sponsor	SolasCure Ltd Wellington House East Road Cambridge CB1 1BH UK
Trial Title	A pilot, randomised, parallel group, study to assess the safety and debridement efficacy and of Aurase Wound Gel (AWG) 24 U/mL compared to Standard of Care in patients with sloughy Venous Leg Ulcers
Trial Number	SC_VLU_003
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SOLASCURE COMMUNICATION PLAN AUTHORISATIONS	
Prepared by:	Signature & Date
Dr. Martyn Wilkinson Biomedical Statistician University Hospitals Birmingham NHS Foundation Trust	Signed by: Martyn Wilkinson 11-Feb-2026 | 16:39:50 GMT Signer Name: Martyn Wilkinson Signing Reason: I approve this document Signing Time: 11-Feb-2026 | 16:39:41 GMT 44B81D1CD68045A593BDF96CD06460E0
Reviewed and Approved by	Signature & Date
David Fairlamb Chief Development Officer, SolasCure	Signed by: 11-Feb-2026 | 09:36:05 GMT Signer Name: David Fairlamb Signing Reason: I approve this document Signing Time: 11-Feb-2026 | 09:36:01 GMT 2118E39608264D3F8124621CD36A8378

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VERSION HISTORY:

Version	Date of Update	Summary of Changes
1.0	11 October 2024	Initial document

LIST OF ABBREVIATIONS

AEs:	Adverse Events
AWG	Aurase Wound Gel (24 U/mL)
CVD	Chronic Venous Disease
ITT	Intention to Treat
PP	Per Protocol
SOC	Standard of Care

1 INTRODUCTION

Chronic leg ulcers are defined as wounds characterised by either delayed healing (typically more than 6-12 weeks) or by wounds which do not heal at all. Most leg ulcers occur because of venous insufficiency due to chronic venous disease (CVD). Compression therapy with dressings and inelastic or elastic bandages remains the gold standard treatment for venous leg ulcers. In common with other chronic wound types, excess wound exudate, necrotic/sloughy wounds, wound infection and wound odour frequently occur in leg ulcers.

Aurase Wound Gel is intended to be used as part of a new generation of wound bed preparation products, specifically intended for both initial and maintenance debridement of wounds covered with fibrinous slough or eschar and thus facilitate healing.

2 OVERVIEW & OBJECTIVES OF STUDY DESIGN

The primary objective of the study is to ascertain the systemic and local adverse event profile of the 24U/mL Aurase Wound Gel concentration.

A secondary objective is to assess the debridement efficacy of 24U/mL Aurase Wound Gel compared to standard of care over 4 weeks of treatment. A further secondary objective is to contrast the healing potential of 24U/mL Aurase Wound Gel with standard of care (SOC). An exploratory objective is to gauge the effect of treatment on quality of life.

3 SAMPLE SIZE JUSTIFICATION

Using an assumption of >60% mean debridement (±25%) and >60% mean partial area reduction (±25%) within 4 weeks for Aurase Wound Gel and a mean of 20% debridement and partial area reduction for standard of care (ActivHeal), a revised (reduced) sample size of 20 patients is calculated to achieve 80% power with an overall alpha of 5%.

4 RANDOMIZATION, STRATIFICATION, BLINDING, AND REPLACEMENT OF PATIENTS

Although the study is not blinded, the 20 patients planned for entry into the study are randomised based on their randomisation number. Patients will only be randomised to the study once eligibility has been confirmed at the baseline visit. The enrolment numbers will follow the format 01-001, 01-002, 01-003 etc through to 01-0020.

Four patients will be randomised to SOC (ActivHeal) and 16 patients to Aurase Wound Gel 24U/mL. An initial randomisation list was prepared in Dec 2025, however based on a documented risk-assessment, and in consultation with the study statistician, the Sponsor implemented a revised randomisation list, prepared on the 20 March 2025, to ensure that the first patient received active treatment. This was performed to evaluate safety of Aurase 24U/mL in conjunction with a compassionate use program. Re-randomisation was considered to have negligible effect on the study outcome on the basis that (i) the study is unblinded in any event (ii) the SC_VLU_003 is a Phase IIA study (iii) the preparation of the revised randomisation list occurred **before** the first patient had their eligibility confirmed for the study.

The revised randomisation list is as follows:

Enrolment_number	Treatment
01-001	Aurase Wound Gel
01-002	Aurase Wound Gel
01-003	ActivHeal
01-004	Aurase Wound Gel
01-005	ActivHeal

Enrolment_number	Treatment
01-006	Aurase Wound Gel
01-007	Aurase Wound Gel
01-008	Aurase Wound Gel
01-009	Aurase Wound Gel
01-010	Aurase Wound Gel
01-011	Aurase Wound Gel
01-012	ActivHeal
01-013	Aurase Wound Gel
01-014	Aurase Wound Gel
01-015	Aurase Wound Gel
01-016	ActivHeal
01-017	Aurase Wound Gel
01-018	Aurase Wound Gel
01-019	Aurase Wound Gel
01-020	Aurase Wound Gel

This list was generated using R version 4.4.1

Participants who are randomised and subsequently withdrawn for safety reasons will not be replaced. Participants who withdraw from the clinical study for other reasons may be replaced with the permission of the Sponsor.

5 DEFINITIONS OF PATIENTS POPULATIONS TO BE ANALYSED

Four patient population sets are planned for analysis:

a) **Enrolled Population**: Consisting of all subjects consented to the clinical trial at screening, and involved in the run-in period, including screen failures and subjects that did not go onto receive interventional treatment.

b) **Safety population** - Consisting of all subjects administered at least one dose of investigational product and have at least one post-dose safety assessment.

c) **Intent to Treat** (ITT) population - Consisting of subjects who are randomised, receive at least one dose of investigational product, and have at least one assessment of efficacy measures.

d) **Per Protocol** (PP) population – A subset of the ITT population consisting of subjects who do not have any major protocol violations or missing primary efficacy data.

6 ENDPOINTS

The primary endpoints are frequency and severity of adverse events (AEs), and frequency and severity of reference wound related local AEs.

The key analyses for efficacy (secondary objective) will be undertaken on the mean reduction of slough area [as a proportion of baseline slough area] achieved over the 4 week period (i.e. the debridement efficiency of treatment) and the mean reduction in wound surface area (cm2) compared to the baseline surface area (i.e. the partial area reduction of the wound). An additional secondary endpoint will assess the proportion of patients that achieve “complete debridement”. The null hypothesis is that there is no difference between the two arms (Group 1 and Group 2).

The alternative hypothesis is that there is a significant difference between at the two arms

Exploratory endpoints comprise changes in the scores of Wound-QoL and Forgotten Wound from baseline at 3 weeks of treatment.

7 STATISTICAL ANALYSIS

The primary analysis of safety, will be based solely on descriptive statistics (frequency of events, and severity of events) in the respective safety populations.

Secondary efficacy analysis in respect of partial area reduction, debridement efficiency and granulation tissue will be assessed using a Generalised Additive Mixed Model (GAMM), a type of mixed effects model that contains random effects for subject and fixed effects comprising a factor for treatment (AWG or ActivHeal) and smoothing splines for each treatment. The random effects will comprise random intercepts and slopes.

Other secondary endpoints will also be analysed using non-parametric models (Wilcoxon rank sum exact test; Fishers exact test).

The primary efficacy analysis will be performed using the ITT population; a sensitivity analysis will be performed using the PP population.

As a Phase IIA study, no allowance has been made for multiplicity of testing.

7.1 Missing Data

Any data missing from the primary analysis will be managed as follows:

- any participants achieving complete debridement within the 3-week period will have their data imputed as Last Observation Carried Forward; i.e. complete debridement will be assumed for the remaining observations in the 3 week period through to the primary endpoint
- where patients discontinue treatment prior to the end of the 3 week period, remaining visits will be imputed based on Last Observation Carried Forward.

8 INTERIM ANALYSIS

No interim analyses are planned as part of this study.

9 STATISTICAL PACKAGES

R version 4.4.2 or higher will be used for all statistical analyses and graphics.