DESCAR Basic Results Summary

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Sponsor:	University of Birmingham
Sponsor reference number:	RG_18-241
Chief Investigator:	Professor Naiem Moiemen
CRCTU reference number:	XX1004
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Clinical Trial Summary Report

Acronym:	DeScar
Title:	A first in human subjects clinical trial of a bioactive dressing designed to reduce scarring of skin burns
Sponsor:	University of Birmingham
Sponsor Reference Number:	RG_18-241
REC Reference Number:	23/NE/0030
Details of Investigational Medicinal Products:	• Gel-SOLO – Gellan dressing without active anti-scarring agent (vehicle with possible therapeutic effects – non-pharmacological) • Gel-PLUS – Gellan dressing plus active anti-scarring agent Galacorin (a synthetic version of the human protein, decorin) at 4.9mg (IMP) • Urgotul (Standard of Care (SoC) dressing)
Details of Trial Arms:	Stage 1: Sequential phase I safety trial of Gel-SOLO dressing vs. SoC dressing Stage 2: Sequential phase I safety trial of Gel-PLUS dressing vs. SoC dressing Stage 3: Randomised Controlled Pilot (RCP) phase IIa trial with three arms: • Gel-SOLO vs. Gel-PLUS dressings • Gel-SOLO vs. SoC dressings • Gel-PLUS vs. SoC dressings
Start Date: *Date trial opened to recruitment*	Not applicable as the trial never opened to recruitment
End of Trial: *Date of declaration of the end of the trial*	Global end of trial date: 31-Mar-2026 Declaration of End of Trial submission date: 31-Mar-2026

This report was prepared by the Chief Investigator and the Cancer Research UK Clinical Trials Unit (CRCTU) on behalf of the Sponsor.

Contact Details

DeScar Trial Office

D^{3}B Team (Drugs, Diagnostics, Devices and Biomarkers)

Cancer Research UK Clinical Trials Unit (CRCTU), 5th Floor, Open Plan East, Institute of Translational Medicine (ITM), Mindelsohn Way, Edgbaston, Birmingham, B15 2TH

✉: DeScar@trials.bham.ac.uk

☎ 0121 371 8109

☎ 0121 371 8468

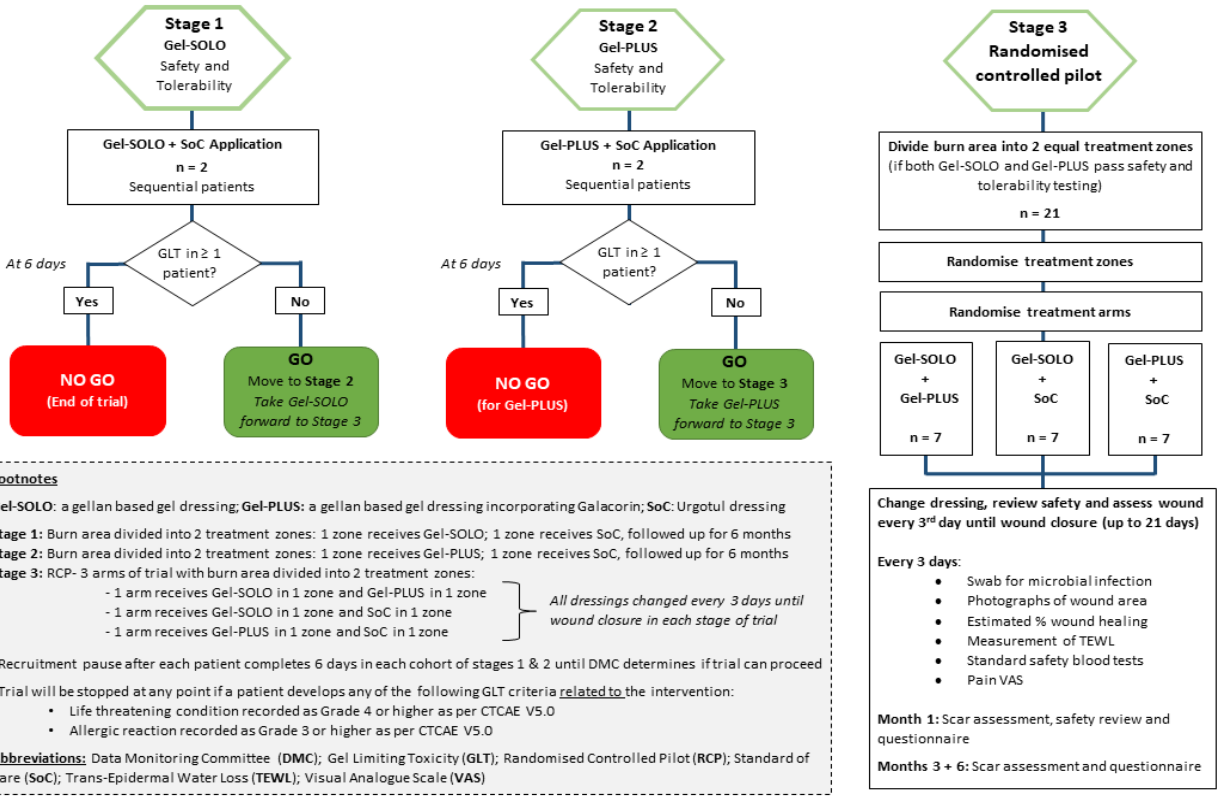
General Note:

The Sponsor terminated the trial early as the manufacturer could not produce the Investigational Medicinal Products (IMPs). The study never opened to recruitment; therefore, no participants were enrolled and no clinical data on the use of the IMP in humans were generated. Consequently, a Clinical Study Report containing results cannot be produced.

This document has been prepared solely to meet the requirement for a Clinical Study Report to accompany the End of Trial declaration, enabling submission of the Final Report form through the Combined Review System. It contains no results.

Trial Design

This is a first in human, open-label, blindly evaluated, prospective, randomised-controlled, single centre clinical trial to intra-individually compare the tolerance and safety of the Gel-SOLO and Gel-PLUS gellan dressings in accelerating the wound healing of superficial partial thickness thermal burn wounds, versus the Standard of Care (SoC) dressing, Urgotul. Ahead of the randomised stage commencing, two safety stages will confirm that there are no adverse safety or toxicity issues with Gel-SOLO (Stage 1) or Gel-PLUS (Stage 2).



Footnotes

Gel-SOLO: a gellan based gel dressing; **Gel-PLUS:** a gellan based gel dressing incorporating Galacorin; **SoC**: Urgotul dressing

Stage 1: Burn area divided into 2 treatment zones: 1 zone receives Gel-SOLO; 1 zone receives SoC, followed up for 6 months
Stage 2: Burn area divided into 2 treatment zones: 1 zone receives Gel-PLUS; 1 zone receives SoC, followed up for 6 months
Stage 3: RCP- 3 arms of trial with burn area divided into 2 treatment zones:
- 1 arm receives Gel-SOLO in 1 zone and Gel-PLUS in 1 zone
- 1 arm receives Gel-SOLO in 1 zone and SoC in 1 zone
- 1 arm receives Gel-PLUS in 1 zone and SoC in 1 zone

All dressings changed every 3 days until wound closure in each stage of trial

*Recruitment pause after each patient completes 6 days in each cohort of stages 1 & 2 until DMC determines if trial can proceed

*Trial will be stopped at any point if a patient develops any of the following GLT criteria related to the intervention:
- Life threatening condition recorded as Grade 4 or higher as per CTCAE V5.0
- Allergic reaction recorded as Grade 3 or higher as per CTCAE V5.0

Abbreviations: Data Monitoring Committee (**DMC**); Gel Limiting Toxicity (**GLT**); Randomised Controlled Pilot (**RCP**); Standard of Care (**SoC**); Trans-Epidermal Water Loss (**TEWL**); Visual Analogue Scale (**VAS**)

Scientific Background

Hypertrophic scar results from the overproduction and poor organisation of collagen by fibroblasts during wound healing, which in turn inhibits wound closure. This process is driven by increasing levels of the cell-signalling molecule, Transforming Growth Factor β1 (TGF-β1) following injury. Decorin is a small proteoglycan and functions within wound healing by binding to and dampening TGF-β1 and facilitates organisation of new collagen. In animal models, Decorin has been shown to reduce tissue fibrosis and inflammation and encourage tissue regeneration. We have developed a dressing containing a synthetic version of decorin, called Galacorin, designed to help reduce scar formation in skin. The dressing is formed of gellan, a polysaccharide already used in eye drops and the food industry as a viscosity modifying agent. Unlike existing silicone and polyurethane based burns dressings, this technology can be used as a platform for concurrent delivery of treatments, such as Galacorin, to the wound. The dressing exhibits viscoelastic properties that allowed it to be draped on an irregular wound bed with good conformity and is semi-permeable. This avoids the accumulation of tissue fluid that is the leading cause of infection. The dressing is transparent, allowing the burn to be visually assessed whilst it is in-place, and does not adhere to the wound's surface, allowing for easy removal. To date we have: (i) demonstrated sustained Galacorin release from these dressings and in vitro and in vivo inhibition of scar formation; (ii) established from pre-clinical studies designed in accordance with ICH M3 (R2) that there are no systemic or local toxicity effects from the dressing both with and without Galacorin and (iii) developed a GMP-compliant scaled-up manufacturing process.

This phase I and phase IIa clinical trial will demonstrate the safety and tolerability of the dressing for thermal burns patients. The trial will also look at whether it improves the burn's healing time and reduces scarring, when compared to the current Standard of Care dressing, Urgotul. If successful, this project will pave the way for a phase 3 multi-centre clinical trial.

Trial Rationale

Individuals with partial thickness burns can have their wound depth and time to wound healing accurately assessed objectively. As a routine clinical practice these wounds are regularly assessed, cleaned and dressed. Current treatment options for this patient population is sub-optimal. Testing a novel dressing in this patient population will allow defined measurements of these endpoints to ascertain safety and tolerability, along with some markers of efficacy.

The primary objective of this first-in-human trial is to assess safety. The trial therefore includes two safety and toxicity stages evaluating Gel-SOLO (Stage 1) and Gel-PLUS (Stage 2) in sequential sentinel patients with partial thickness burns respectively prior to a randomised controlled trial (Stage 3). Stage 3 is a three arm, assessor-blinded, prospective, randomised-controlled trial comparing the gellan dressing both with and without Galacorin to Standard of Care (SoC) dressing in accelerating the wound healing of partial thickness burn wounds. The design of having 3 arms will allow examining whether gellan alone without Galacorin has any beneficial effect on wound healing and infection. Both SoC and the interventional dressings do not leave a visible marking around the wounds once removed. This will reduce the observer bias.

The justification for using the gellan dressing without Galacorin is two-fold. Firstly, once reconstituted and applied to the skin, the dressing provides a transparent, semi-permeable barrier that can conform to an irregular wound bed and facilitates hydration of the wound area similar to other hydrogel and hydrocolloid dressings on the market. The ability to ensure wounds remain moist (but not macerated) with exudate, free of clinical infection and excessive slough, free of particles or fibres, and at the optimum temperature for healing are well known desired characteristics of wound dressings in general. Secondly, results from a mid-depth porcine burn

model surprisingly showed that the negative control group (gellan dressing without Galacorin) healed with less scarring than the current standard of care dressing on the skin. For the avoidance of any doubt, the current standard of care does not make any claims regarding scar prevention or reduction. However, the relative improvement in scar outcome between these dressings justifies the inclusion of a gellan dressing without Galacorin in the trial to explore the effects of the gellan dressing as a vehicle from the effects of the Galacorin.

Gel-SOLO (i.e. gellan without the active ingredient) is considered to be a vehicle control for the trial. It is recognised and accepted that patients may derive clinical therapeutic benefit from the vehicle control as seen with other wound dressings, but these benefits are likely to be driven through physical rather than pharmacological mechanisms.

The justification for a gellan dressing containing Galacorin (Gel-PLUS) is based on peer-reviewed in vitro and in vivo animal studies carried out on the general / native decorin protein by both the team involved in this trial and independently by the wider scientific and clinical academic community. Decorin has been shown to accelerate wound healing in vitro and in vivo in animal studies. Superficial partial thickness burns that heal within 10 days after the injury are unlikely to result in long term scarring. Eighty percent of deep partial thickness burns that do not heal within 21 days will have long term scarring and the majority will require skin grafting to achieve wound closure. Therefore, this trial will also examine the potential effect of Galacorin on the rate of wound healing and scar formation compared to a Standard of Care dressing.

Objectives

PRIMARY OBJECTIVES:

1. To assess the safety of Gel-SOLO and Gel-PLUS dressings, intra-individually, compared to Standard of Care (SoC; Urgotul) dressing.
2. To assess the tolerability of Gel-SOLO and Gel-PLUS dressings, intra-individually, compared to Standard of Care (SoC; Urgotul) dressing.

SECONDARY OBJECTIVES:

1. To assess time to wound closure compared to SoC.
2. To assess long term scarring compared to SoC.

OUTCOME MEASURES

PRIMARY OUTCOME MEASURES

Safety will be assessed by:

- Occurrence of Gel Limiting Toxicity (GLT) defined as the occurrence of any of the following during the 6-day assessment window that is determined as related to Gel-SOLO or Gel-PLUS as applicable:
  - Life threatening condition recorded as Grade 4 or higher as per CTCAE V5.0 (Appendix 1)
  - Allergic reaction recorded as Grade 3 or higher as per CTCAE V5.0 (Appendix 1).
- Microbial colonisation as confirmed by numerating colony-forming units from microbiology swab samples at screening and at each dressing change

Tolerance will be assessed by:

- A pain Visual Analogue Scale (VAS) evaluated by participants after each dressing change.

SECONDARY OUTCOME MEASURES

For secondary objective #1 – to assess wound healing progress:

1. Time to 95% wound healing subjectively assessed using:
    - Independent, real time visual clinical assessment of percentage wound healing
    - 2D photograph assessment of percentage wound healing – assessed by three independent, blinded assessors.
2. Rate of wound healing will be measured objectively at three areas per wound half (the periphery, mid-zone and centre of wound), using:
    - Measurement of transepidermal water loss (TEWL) by Tewameter

For secondary objective #2 – to assess rate and severity of pathological scarring of the wounds post-healing:

1. Scar size measured by calculating scar surface area
2. Objective measurement of scar quality at the periphery, mid-zone and centre from time of complete wound healing to 6 months using:
    - DermaScan high frequency ultrasound for scar thickness.
3. Subjective measurement of scar quality from time of complete wound healing to 6 months using the following questionnaire:
    - Brisbane Burn Scar Impact Profile (BBSIP) score.

- Statistical Considerations

  Not applicable as the trial never opened to recruitment

- Trial Population

  Not applicable as the trial never opened to recruitment

SUBJECT DISPOSITION

ELIGIBILITY CRITERIA

Main inclusion criteria:

1. Male or female patients aged ≥ 16 years old
2. Superficial partial thickness thermal burns covering 3-20% of TBSA determined by clinical judgement.

MAIN EXCLUSION CRITERIA:

1. Deep/full thickness burns
2. Burn injury occurred more than 72 hours before planned treatment start
3. Chemical burns, electrical burns or cold burns
4. Burns of the head, neck, hands, feet or genitalia

5. Presence of obvious clinical infection in the wound (clinical judgement)

RECRUITMENT

Not applicable as the trial never opened to recruitment

WITHDRAWALS

Not applicable as the trial never opened to recruitment

BASELINE CHARACTERISTICS

Not applicable as the trial never opened to recruitment

ENDPOINTS

Not applicable as the trial never opened to recruitment

ADVERSE EVENTS

Not applicable as the trial never opened to recruitment

MORE INFORMATION

Not applicable as the trial never opened to recruitment

CONCLUSIONS

Not applicable as the trial never opened to recruitment

DISSEMINATION

Not applicable as the trial never opened to recruitment

REFERENCES

None