

# A first in human subjects clinical trial of a bioactive dressing designed to reduce scarring of skin burns

<b>Submission date</b> 13/01/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/04/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/01/2024	<b>Condition category</b> 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

This trial is looking at new ways to improve the healing of skin burns caused by heat. After the wound has healed, scarring may remain that can be uncomfortable, effect free movement and cause psychological problems. Standard burn dressings only stop the wound from drying out and getting infected, but they can't actively help the healing process along and reduce scarring. We have developed new kinds of dressing made from clear gel that we think may be able to reduce scar formation. Because our gel dressing is soft and floppy, it sits snugly on the wound and allows excess moisture to escape. We think that these properties may reduce the risk of infection and may help the wound to heal more quickly and with less scarring.

As well as this basic gel dressing we also want to test another version of it that has an active healing substance added into it. We all have a naturally occurring substance that is produced by our bodies to help with skin healing, called Decorin. Our research team has made an identical manmade version of Decorin and we want to see if adding this into the new gel dressing might boost its healing performance and reduce scarring even more than just the gel alone.

The aim of the trial is to find out if these two new burn dressings are safe and comfortable for patients, and whether they can speed up healing and reduce scarring compared to the standard NHS burn dressing.

### Who can participate?

Burns patients aged 16 years or more, male or female, coming for treatment for recent second-degree (called 'partial thickness') heat burns covering 3-20% of their body.

### What does the study involve?

For each of the 25 volunteer patients taking part, the study will last for 6 months. We will be comparing 3 weeks of treatment using 2 new gel-based wound dressings with the standard NHS dressing, and then assess how well the wound has healed at 3 follow-up appointments.

The two new dressings we have developed for testing are called 'Gel-SOLO', which is the gel on its own and 'Gel-PLUS', which is the same gel but with lab-made decorin added to it. We will be comparing our two new dressings with the standard NHS burn dressing, to see if they are safe and comfortable for patients, and how well they help the healing process.

Each volunteer will have different burn areas treated with two of the study dressings, but to keep the study objective they won't know exactly which ones they have. During the 3 week treatment period the research team will do regular medical checks and assessments. These include taking scans and photos of the wounds to track size and depth, taking swabs to check there is no infection, doing routine blood tests, and asking patients to complete questionnaires about pain levels and the impact the burns have on 'quality of life' experience. Participants will come to the burns centre at Birmingham's Queen Elizabeth Hospital every 3 days for a period of up to 3 weeks. After that there will be 3 more clinic visits at Months 1, 3 and 6, for the team to do more follow-up checks and measurements to see whether there is any difference in the scar size and quality with the different dressings that were used.

What are the possible benefits and risks of participating?

Benefits: if the new gel burn dressings do work better than the standard NHS dressing, then participants may have a faster speed of recovery and there is also a possibility they may have less scarring left behind.

Risks: the potential risks for participants in this trial are: (1) there may be side effects from having the treatment. Since this is the first time the new gel dressings are being used to treat patients, there is limited information available on what side effects there might be, although we think these could include itchiness, redness or swelling of the wound; (2) the treatment may not be effective; and (3) the two treatment areas may heal at different rates and any scars remaining could look and/or feel different over the longer term. The main burden for participants will be needing to come to the burns centre for around 12 clinic appointments and undergoing medical checks and assessments needed for the research.

Where is the study run from?

University of Birmingham (UK)

When is the study starting and how long is it expected to run for?

January 2023 to February 2026

Who is funding the study?

The Scar Free Foundation (UK)

Who is the main contact?

Prof Naiem Moiemman, N.Moiemen@bham.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Naiem Moiemman

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2019-004076-19

### Integrated Research Application System (IRAS)

1004584

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

RG\_18-241, IRAS 1004584

## Study information

### Scientific Title

A first-in-human clinical trial of a bioactive dressing designed to reduce scarring of skin burns

### Acronym

DeScar

### Study objectives

Primary objective:

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

Secondary objectives:

1. To assess time to wound closure compared to Standard of Care.
2. To assess long term scarring compared to Standard of Care.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 05/04/2023, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne , NE2 4NQ , United Kingdom; +44 (0)207 104 8384; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 23/NE/0030

### Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Superficial partial thickness thermal burn(s) between 3-20% Total Body Surface Area

## Interventions

The DeScar trial is made up of three stages, and will involve 25 volunteer participants with heat burn wounds covering 3-20% of their body surface. All of the burn dressings used will be 10cm x 10cm in size. For each participant, two burn areas will be selected for study treatment, with a different type of dressing used on each area for comparison. In all 3 study stages, dressings will be changed every 3 days for 21 days or until the wound has healed. After treatment, there will be a follow-up period of 6 months for all stages. The three study stages are:

Stage 1: Comparing Standard of Care NHS dressing (called Urgotul) and Gel-SOLO dressing (gel based dressing) in 2 participants.

Stage 2: Comparing Standard of Care NHS dressing and Gel-PLUS dressing (gel based dressing with decorin added) in 2 participants.

Stage 3: Participants randomised via an electronic database to receive either:

- Standard of care NHS dressing and Gel-SOLO dressing; 7 participants
- Standard of care NHS dressing and Gel-PLUS dressing; 7 participants
- Gel-SOLO dressing and Gel-PLUS dressing; 7 participants

## Intervention Type

Biological/Vaccine

## Phase

Phase I/II

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

Gel-SOLO, Gel-PLUS [Human recombinant decorin (tradename: Galacorin™)]

## Primary outcome(s)

Safety will be assessed by:

1. 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
2. Microbial colonisation as confirmed by numerating colony-forming units from microbiology swab samples at each dressing change

Tolerability will be assessed by:

1. A pain Visual Analogue Scale (VAS) evaluated by patients before the dressing change visits and within 15 minutes of the new dressing being applied

## Key secondary outcome(s)

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

1. Time to 95% wound healing subjectively assessed using:
  - 1.1. Independent, real time visual clinical assessment of percentage wound healing
  - 1.2. 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. Scar quality using a panel of objective scar measurement devices at the periphery, mid-zone and centre from time of complete wound healing to 6 months (DermaScan high frequency ultrasound for scar thickness)
3. Subjective measures of scar quality from time of complete wound healing to 6 months using the Brisbane Bars Scar Impact Profile (BBSIP) Score.

### **Completion date**

09/02/2026

## **Eligibility**

### **Key inclusion criteria**

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

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Sex**

All

### **Key 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)
6. Poly-trauma with Injury Severity Score (ISS)  $>25$

7. Mechanically ventilated patients
8. Co-morbidities which may interfere with the aim(s) of the trial. Examples include skin conditions such as pathological fibrosis, e.g. scleroderma; pathological thinning, e.g. epidermolysis, bullosa, and collagen disorders
9. Patients on immunosuppressant therapy
10. Chronic steroid use, history of skin malignancy or chronic papulosquamous disease (e.g. eczema, pemphigus), and history of Stevens-Johnson syndrome (SJS) or Toxic Epidermal Necrolysis (TEN) disease
11. Participation in another interventional trial (IMP/medical device), which may affect the results of this trial
12. A history of clinically significant hypersensitivity to any of the components of the trial dressings or procedural medication used in this trial
13. Known multiple allergic disorders
14. Not willing or able to comply with the trial visits and assessment schedule
15. Mental incapacity or language barriers precluding adequate understanding or co-operation or willingness or ability to follow trial procedures.
16. Any other reason that the clinician considers will interfere with the objectives of the trial
17. A woman who is pregnant or breastfeeding
18. A woman of child-bearing potential (WOCBP) who does not agree to use a highly effective method of birth control during heterosexual intercourse from screening until 30 days after last trial treatment.
19. A male who is not vasectomised and does not agree to use barrier contraception (condom plus spermicide) during heterosexual intercourse from screening until 30 days after last trial treatment.

**Date of first enrolment**

09/04/2024

**Date of final enrolment**

09/09/2025

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University Hospitals Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2GW

# Sponsor information

## Organisation

University of Birmingham

## ROR

<https://ror.org/03angcq70>

# Funder(s)

## Funder type

Charity

## Funder Name

Scar Free Foundation

## Alternative Name(s)

The Scar Free Foundation, The Healing Foundation, SFF

## Funding Body Type

Government organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Access to study data will be in accordance with the university of Birmingham and CRUK clinical trial unit (CRCTU) data sharing policy:

<https://www.birmingham.ac.uk/research/crctu/data-sharing-policy.aspx> . The CRCTU has a defined procedure in place for data sharing which ensures that the necessary legal and ethical requirements are followed, this policy which is based on guidelines published by the Information Commissioners Office.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[HRA research summary](#)

20/09/2023

No

No