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

Submission date
13/01/2023

Recruitment status
Recruiting

Registration date
25/04/2023

Overall study status
Ongoing

Last Edited
29/01/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 Moieman, N.Moiemen@bham.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Naiem Moiemen

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Additional identifiers

EudraCT/CTIS number
2019-004076-19

IRAS number
1004584

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
09/01/2023

Completion date
09/02/2026

Eligibility

Key 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

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex

Both

Target number of participants
25

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
England

United Kingdom

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
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Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
University of Birmingham

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

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

Publication and dissemination plan
Peer reviewed scientific journals
Conference presentation
Publication on website
Submission to regulatory authorities
Accessible Summary of Study Results, written in plain English

Intention to publish date
31/10/2026

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?
HRA research summary			20/09/2023	No	No