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A clinical study of a new dressing (GellanAA) for the treatment of burn wounds

Submission date
27/01/2025

Recruitment status
Recruiting

Registration date
31/01/2025

Overall study status
Ongoing

Last Edited
03/09/2025

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Infection after a burn injury is common and can have devastating consequences for patients and their families. Up to 42% of burn injury patients get an infection, which may progress to sepsis and up to 65% of sepsis patients do not survive. Infection happens because the top layer of the skin provides a barrier that prevents infection. When skin is burnt, this layer is destroyed, leaving patients at a higher risk of infection until it is fully healed. The aim of this study is to explore the effectiveness of a new type of dressing with acetic acid (vinegar) to keep burn wounds free of injection while they are healing.

Who can participate?
Patients aged 16 years and over with superficial partial thickness thermal burns

What does the study involve?
In this project, the team will use a new approach developed at the University of Birmingham to apply a constant dose of acetic acid to a burn wound via a clear dressing. The dressing can be used to kill germs for up to three days at a time without the need for painful dressing changes twice a day. Participants in the study will have part of their wound treated with the new dressing. The rest of the burn wound will receive the standard dressing. The clinical team will compare the two different areas for any infection and measure the healing, scar development and levels of pain. The participants and the medical team checking the wound for healing will not be told which area has been treated with acetic acid so that they can judge both areas fairly.

What are the possible benefits and risks of participating?
Benefits:
This study will assess whether using the GellanAA burn dressing is safe and will assess its impact on burn wound healing compared to using the standard dressing treatment. If the new Gel treatment (GellanAA) is effective then your speed of recovery may be faster and there is also a possibility that you may have less scarring on the wound.
Risks:
1. Possible side effects from having the treatment.
2. The treatment may not be effective.
3. Needing to attend multiple clinic appointments on specific days (with some limited date

flexibility) and undergoing additional study-related assessments. The two follow-up checks at the end of the study are in addition to standard care.
4. The two treatment zones may heal at different rates and could look and/or feel different over the longer term.

Where is the study run from?
The clinical visits and assessments will be run from the Queen Elizabeth Hospital, Birmingham. The study management team will manage the project from the University of Birmingham (UK).

When is the study starting and how long is it expected to run for?
April 2022 to March 2026

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mrs Amandip Malhi, a.malhi@bham.ac.uk

Contact information

Type(s)

Contact name
Mrs Amandip Malhi

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326659

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 59929, NIHR203395

Study information

Scientific Title
An open, first-in-human, blind-evaluated, single-centre, randomised, controlled, clinical Investigation to evaluate the safety and performance of GELLAN/Acetic Acid dressing in the treatment of burn wounds

Acronym
GellanAA

Study objectives
No formal hypotheses testing as this study is primarily a feasibility study (first in man) testing the safety and efficacy of the novel anti-microbial burn wound dressing (GellanAA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/02/2024, East of England – Cambridge Central REC (HRA, 2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8285, +44 (0)207 104 8089, +44 (0)207 104 8063; cambridgecentral.rec@hra.nhs.uk), ref: 23/EE/0270

Study design
Non-randomized; Interventional; Design type: Treatment, Screening, Device

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Burn wounds

Interventions
Patients will be identified at the Queen Elizabeth Hospital Birmingham (QEHB). Potentially eligible participants with a burn of 2-25% TBSA will be approached by a member of the site burns team. Participants should be entered into the study after the results of the screening process are available and this should be less than 48 hours before planned treatment start.

For patients who appear to meet the criteria for participation in the study, the Investigator will provide the potential participant with the current approved Participant Information Sheet to allow them to make an informed decision regarding their participation. If informed consent is given, the Investigator will conduct a full screening evaluation to ensure that the patient satisfies all inclusion and exclusion criteria.

The investigator will select a superficial partial thickness burn of between 2-25% of the participant's total body surface area (TBSA) that can be divided into two zones measuring at least 10 x 10 cm each with a 2 cm gap in between. If this is not possible, two separate but comparable contralateral 10 x 10 cm burn zones can be selected.

Each zone of the participant's burn area will then be randomised to receive one of the two dressings. This information will be recorded in the participant's medical notes and on the registration/randomisation case report form (CRF). The remaining areas of the wound(s) not covered by the experimental dressing (including the 2 cm gap between the two test dressings) will be covered with the Standard of Care dressing so that no part of the wound is left exposed during the healing process. The dressing will be applied by the study nurses on the ward or in an outpatient clinic depending on whether the participant has been discharged.

Visit Schedule
Visit 1: Baseline/Start of treatment (≤48 hours post burn injury [Day 0])
Visit 2 (3 days after Visit 1 [+/- 2 days])
Visits 3a, 3b, 3c, 3d, 3e (every 3 days (+/- 2 days) until full wound closure or Day 21 post burn)
Visit 4: End of treatment: full wound closure or Day 21 (+/- 2 days) post burn
Visit 5: 1 month follow up (Day 28 post burn +/- 3 days)
Visit 6: 3 month follow up (Day 84 post burn +/- 3 days)

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
GellanAA dressing

Primary outcome measure
The safety and performance of GellanAA dressing, compared to Urgotul silver (Standard of Care) dressing measured whereby the safety will be assessed by the occurrence of any hypersensitivity or gel-limiting toxicity and the microbial colonisation at each wound change. Performance will be measured using a pain Visual Analogue Scale (VAS) at each wound change.

Secondary outcome measures
1. Early wound healing measured using photography of wound area (at all visits), microbial swabs at baseline (Visit 1), Visit 2, and Visits 3a-3e
2. Scarring at 3 months after injury assessed by measuring the scar surface area at Visits 4, 5 & 6 and performing a Dermascan at visits 5 & 6

Overall study start date
01/04/2022

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. >=16 years of age
2. Superficial partial thickness thermal burns covering 2-25% of TBSA determined by clinical assessment by a senior member of the team caring for the individuals
3. Male and female participants of childbearing potential willing to use highly effective contraception
4. Participants willing and able to comply with scheduled visits, treatment plan and other study procedures
5. Written informed consent for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Deep/full thickness burns
2. Burn injury occurred more than 48 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. Comorbidities which may interfere with the aim(s) of the study. 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 study (IMP/medical device), which may affect the results of this study

12. A history of clinically significant hypersensitivity to any of the components of the study dressings or procedural medication used in this study
13. Known multiple allergic disorders
14. Not willing or able to comply with the study visits and assessment schedule
15. Mental incapacity or language barriers precluding adequate understanding or co-operation or willingness or ability to follow study procedures.
16. Any other reason that the clinician considers will interfere with the objectives of the study
17. A woman who is pregnant or breastfeeding

Date of first enrolment
01/03/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
Queen Elizabeth Hospital Birmingham
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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
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be published in an applicable medical journal and a lay summary of the results will be produced and disseminated at various conferences and public engagement events.

Intention to publish date
31/03/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from a request to the study trial management group in accordance with the CRCTU data sharing policy: https://www.birmingham.ac.uk/research/centres-institutes/cancer-research-uk-clinical-trials-unit/data-sharing-policy

IPD sharing plan summary
Available on request