ISRCTN42000162 https://doi.org/10.1186/ISRCTN42000162

Using ultrasound to improve antibiotic treatment in infected burns: a feasibility study

Submission date
25/11/2025

Recruitment status
Not yet recruiting

Registration date
17/02/2026

Overall study status
Ongoing

Last Edited
17/02/2026

Condition category
Infections and Infestations

[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
This study will assess whether ultrasound-activated microbubbles with antibiotics are safe, and whether a larger scale study is feasible. Some indications of the impact of the use of ultrasound-activated microbubbles with antibiotics on patient recovery will also be made.

Who can participate?
The study will include adults aged 18 or older who are admitted to the regional burn unit at Buckinghamshire Healthcare NHS Trust. They must have a clinically infected superficial or partial-thickness thermal burn affecting no more than 4% of their total body surface area.

What does the study involve?
People with small, infected burns will be randomly assigned to receive either microbubbles with antibiotics or a placebo (a treatment that looks the same but has no active medication). The treatment will be given alongside normal wound care and antibiotics. Researchers will check for any side effects, see how easy it is to use the treatment, and measure how well the infection heals. If this study is successful, it could lead to larger trials and, in the future, a new way to treat infections more effectively.

What are the possible benefits and risks of participating?
Benefits:
Not provided at time of registration
Risks:
Participation in this study is not expected to involve significant risks beyond normal hospital treatment for an infected burn. However, some temporary discomfort or inconvenience may occur. The following outlines possible risks and the steps taken to minimise them.
1. Physical discomfort or local skin irritation
The study involves applying a gel containing microbubbles and, in some cases, gentamicin to the burn wound, followed by a brief ultrasound treatment (30 seconds–2 minutes). Some participants may experience mild warmth, stinging, or tenderness.
Minimisation: Treatments will be performed by trained staff under sterile conditions, using clinically approved equipment and low ultrasound settings. Participants will be monitored during and after treatment, and any discomfort or reaction will be promptly managed using standard

care.
2. Allergic reactions
A small number of people may be allergic to one of the products used (gentamicin, microbubble contrast, or the gel base).
Minimisation: All participants will be screened for known allergies or sensitivities before enrolment. Anyone with a history of allergy to these products will be excluded. Emergency equipment and trained staff will be available if a reaction occurs. The likelihood of allergy is very low as these products are routinely used in the NHS.
3. Theoretical risk of bacterial spread or systemic infection
There is a theoretical risk that ultrasound could temporarily increase tissue permeability and allow bacteria to move deeper into the skin.
Minimisation: This risk is considered extremely low. Participants will continue to receive standard antibiotics and wound dressings. They will be monitored for any signs of worsening infection or fever, and any concerns will be managed immediately according to standard clinical practice.
4. Blood tests and wound swabs
Participants will have wound swabs taken before and after treatment sessions, and routine blood tests performed as part of normal care. These may cause mild discomfort.
Minimisation: Swabs and blood samples will be collected by experienced staff using standard techniques, timed to coincide with routine procedures to avoid additional burden.
5. Time and inconvenience
All study procedures will occur during the participant's hospital stay, so no extra visits or travel are required. Each treatment session will last around 30–45 minutes, including set-up, treatment, and brief questionnaires.
Minimisation: Procedures will align with routine dressing changes and ward rounds. Questionnaires are brief (under five minutes) and can be completed at the bedside.
6. Confidentiality and data security
Photographs and imaging of the wound will be taken to monitor healing. Although these will be anonymised, there is a minimal risk of loss of confidentiality.
Minimisation: All data and images will be coded using a study ID and stored on secure NHS servers with restricted access. Identifiable features will be excluded wherever possible, and no data will be stored on personal or portable devices.
7. Psychological or emotional distress
Discussing or viewing wound photographs may cause mild distress or embarrassment for some participants.
Minimisation: Participants will be treated sensitively and can choose not to view their images or withdraw from the study at any time without affecting their care.
The overall level of risk is low. All clinical components (ultrasound, gentamicin, and wound care products) are routinely used in NHS practice. Additional study activities (imaging and questionnaires) are minimal, non-invasive, and designed to reduce participant burden. Participants will receive full information about all potential risks before giving consent and may withdraw at any time without affecting their clinical treatment or care.

Where is the study run from?
Buckinghamshire Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
March 2026 to January 2028

Who is funding the study?
NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
Prof Fadi Issa fadi.issa@nhs.net

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Prof Fadi Issa

ORCID ID
https://orcid.org/0000-0002-8279-7732

Contact details
Stoke Mandeville Hospital
Aylesbury
United Kingdom
HP21 8AL
+44 (0)1296 418140
fadi.issa@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
1013208

Study information

Scientific Title
Feasibility of ultrasound-activated microbubble–assisted topical antibiotic delivery in infected partial-thickness burns: a randomised controlled trial.

Study objectives
To assess the safety and feasibility of using ultrasound-activated microbubbles to enhance topical antibiotic delivery in the management of infected partial-thickness burn wounds. The study will determine whether the procedure is safe, well tolerated, and practical to deliver in an inpatient burn care setting, and whether progression to a larger definitive trial is feasible.

To explore the effect of ultrasound-activated microbubbles on wound infection resolution, bacterial load, and healing outcomes. Secondary objectives also include assessing patient tolerability, acceptability, and willingness to use the intervention in future clinical practice, alongside evaluating changes in microbiological findings, wound appearance, and patient-reported outcomes (pain and satisfaction).

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 26/01/2026, London - Dulwich Research Ethics Committee (Health Research Authority 2nd Floor, 2 Redman Place, Stratford, London, E20 1JO, United Kingdom; +442071048276; dulwich.rec@hra.nhs.uk), ref: 25/LO/0907

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Efficacy, Safety, Not Specified

Health condition(s) or problem(s) studied
Medical condition: Infected partial-thickness burn wounds (superficial to deep partial-thickness confluent wounds affecting <4% TBSA).
Medical condition in lay language: Infections in small burn wounds — specifically partial-thickness burns that have become infected and require treatment during hospital admission.
Therapeutic areas: Diseases [C] - Bacterial Infections and Mycoses [C01]

Interventions
This is a single-centre, randomised controlled feasibility study with four parallel arms (1:1:1:1). Participants are inpatient adult burn patients with clinically infected partial-thickness burns managed without skin grafting. All groups receive standard of care, comprising systemic antibiotics as per local burns SOPs, wound cleaning, antiseptic dressing (Bactigras), and routine inpatient monitoring. All arms are followed during admission and routine outpatient care until wound healing.

• Arm 1 Standard of Care (Primary Control, open label): Participants receive standard wound care and systemic antibiotics only. No study gel or ultrasound is applied.
• Arm 2 Standard of Care + Ultrasound-activated microbubbles with gentamicin (Intervention) Participants receive topical gel containing ultrasound-responsive microbubbles (Luminity®) combined with gentamicin 80 mg (40 mg/mL formulation).
Dose: 80 mg gentamicin per application (topical)
Route: Topical application to wound surface
Frequency: Once daily
Duration: Up to 3 treatment sessions
Ultrasound parameters: 1 MHz ultrasound applied for 30 seconds to 2 minutes per treatment site
• Arm 3 Standard of Care + Ultrasound-activated microbubbles without gentamicin (Treatment

Control 1)
Participants receive topical gel containing ultrasound-responsive microbubbles (Luminity®) but without antibiotic.
Route: Topical application to wound surface
Frequency: Once daily
Duration: Up to 3 treatment sessions
Ultrasound parameters: 1 MHz ultrasound applied for 30 seconds to 2 minutes per treatment site
• Arm 4 Standard of Care + Microbubbles with gentamicin without ultrasound activation (Treatment Control 2)
Participants receive topical gel containing ultrasound-responsive microbubbles (Luminity®) combined with gentamicin 80 mg (40 mg/mL formulation) but without ultrasound activation.
Dose: 80 mg gentamicin per application (topical)
Route: Topical application to wound surface

Treatment is delivered once daily for a maximum of three sessions alongside standard care. Participants exit the study at discharge, clinical resolution, completion of treatment, or withdrawal.

Randomisation is performed using a computer-generated sequence with permuted blocks. Allocation is concealed using sequentially numbered sealed envelopes generated via an online randomisation tool. Treatment preparation and the ultrasound unit operation are performed by an unblinded investigator who is not involved in patient care. Investigators, participants, and outcome assessors are blinded across the three treatment arms.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Luminity® [Perflutren (approved INN)] , Gentamicin 10 mg/mL Solution for Injection or Infusion [Gentamicin (INN — approved)]

Primary outcome(s)
1. Safety measured using the incidence of adverse events recorded on electronic Case Report Forms at consent until the end of study participation (hospital discharge or completion of follow-up)

2. Feasibility measured using participant recruitment rate, treatment adherence, and retention rate recorded in study databases at the start of the recruitment period until completion of participant follow-up

Key secondary outcome(s))
1. Wound infection resolution measured using the change in bacterial presence on wound swabs using standard microbiological culture, semi-quantitative growth categorisation (heavy growth, moderate growth, scanty growth), species identification and antimicrobial susceptibility testing at baseline and prior to each treatment session

2. Wound healing rate measured using standard clinical wound assessment (size, depth, infection signs), standardised wound photography, and Laser Doppler Imaging (LDI) perfusion assessment, at baseline and prior to each treatment session until wound healing or discharge

3. Tolerability: Comfort measured using a 0–10 Visual Analogue Scale at after each treatment session

4. Tolerability: Acceptability measured using a Likert scale questionnaire at the end of treatment or discharge

5. Tolerability: Willingness to use treatment in future clinical practice measured using a post-study questionnaire at the end of participation (treatment completion or discharge)

Completion date
01/01/2028

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years.
2. Admitted to the regional burn unit at Buckinghamshire Healthcare NHS Trust.
3. Clinically infected superficial or partial-thickness thermal burn wounds (superficial to deep partial-thickness) affecting ≤4% total body surface area (TBSA).
4. “Clinically infected” is defined by clinical signs observed by the treating team (e.g. erythema, pain, swelling, purulence) and symptoms reported by the patient.
5. Able to provide informed consent and with mental capacity to understand the study requirements.
6. Inpatients with burns being managed without surgical grafting.
7. Patients who have undergone surgical debridement (e.g. Versajet) but not grafting are eligible.
8. Willing and able to comply with study procedures and follow-up during hospital admission.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria

The participant may not enter the study if ANY of the following apply:
Trial design–related:
1. Wounds involving >4% total body surface area (TBSA)
2. Full-thickness or chemical burns
3. Wounds requiring grafting as part of treatment
4. Participation in another clinical trial involving burn treatment or antibiotics

Products:
1. Optilube: Known allergy or hypersensitivity to any component of Optilube
2. Luminity: Known allergy or hypersensitivity to any excipients in Luminity
3. Gentamicin: Known allergy or hypersensitivity to gentamicin or any of its excipients
4. Known contraindication to gentamicin use
5. Concomitant use of nephrotoxic or ototoxic medications
6. History of serious aminoglycoside toxicity
7. Pre-existing auditory or vestibular disease

Ultrasound-related:
1. Presence of metallic implants within or near the treatment area (risk of heating)
2. Presence of other dermatoses in the treatment area (e.g. eczema, psoriasis)
3. Known or suspected pregnancy, or currently breastfeeding
4. Presence of methicillin-resistant Staphylococcus aureus (MRSA) infection
5. Myasthenia gravis
6. Current treatment with immune-modulating drugs (e.g. corticosteroids, anti-rejection therapy, chemotherapy)

Date of first enrolment
31/03/2026

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
England
HP21 8AL

Sponsor information

Organisation

Buckinghamshire Healthcare NHS Trust

ROR
https://ror.org/037f2xv36

Funder(s)

Funder type

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date