

A study to investigate the use of a proprietary wound dressing to reduce ankle swelling to quicken time to surgery

Submission date 29/10/2026	Recruitment status Not yet recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 29/10/2026	Overall study status Ongoing	☐ Statistical analysis plan
		☐ Results
Last Edited 29/10/2026	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims

The aim is to determine whether a proprietary dressing used for the treatment of injuries and known to reduce swelling can be used to ensure that patients, suffering an ankle fracture, are ready for surgery on day 7. This would enable patients to be sent home instead of kept on a ward, which could release up to 90,000 bed days per years as well as making the whole process more efficient.

Who can participate?

Patients aged 18 to 100 years presenting to A&E in the Royal Stoke University Hospital with an unstable ankle fracture

What does the study involve?

Patients will be randomly allocated into two groups. Group 1, the active group, will have the proprietary dressing in addition to any temporary fixation. Those in Group 2 are the control and have not additional dressing. Once the patient is approved for surgery their participation in the study is complete.

What are the possible benefits and risks of participating?

The potential benefit is having an ankle fracture treated earlier than normal (group 1). As the dressing is commonly used in orthopaedics, dermatology and other clinical settings there are no perceived risks from participating.

Where is the study run from?

Royal Stoke University Hospital (UK)

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

November 2026 to May 2027

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Peter J Ogrodnik, p.ogrodnik@keele.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Integrated Research Application System (IRAS)

344827

Study information

Scientific Title

A randomised pilot study to determine the time to surgery when using a polymeric dressing for the alleviation of swelling prior to fixation of an ankle fracture

Acronym

EAH1

Study objectives

The aim of this study is to determine the whether the inclusion of a dressing, known to reduce swelling in other orthopaedic procedures, to patients prior to ankle surgery will reduce the time to operation.

Research question:

What is the average time to surgery for patients treated with PolyMem for an ankle fracture that is too swollen to operate on compared to those not treated with PolyMem?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 31/07/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; edgbaston.rec@hra.nhs.uk), ref: 25/WM/0126

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Prevention, Treatment

Study type(s)**Health condition(s) or problem(s) studied**

Unstable ankle fracture

Interventions

Patients will be randomly divided by scratch card into one of two groups once consent is given. In the control group patients will be treated as per normal practice. In the active group patients will have their fracture additionally wrapped within a PolyMem wrap. This wrap is already in use for the treatment of limb injuries for the acceleration of swelling reduction.

There will be no change to the normal treatment regime for a patient presenting an ankle fracture. All patients will have temporary fixation applied to await surgery. The choice of fixation remains with the lead surgeon: this may be a Plaster-of-Paris Back-Slab or a temporary frame.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Polymem Wrap

Primary outcome(s)

1. Time to 'ready for surgery' measured using observation by qualified surgeon at day 7

Key secondary outcome(s)

1. Pain severity measured using painkillers prescribed and score of 1-10 taken from notes at day 7

Completion date

30/05/2027

Eligibility

Key inclusion criteria

1. Aged 18 to 100 years
2. Lower leg distal fracture requiring surgical intervention that is delayed due to oedema

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

1. Under the age of 18 years
2. Over the age of 100 years
3. Not skeletally mature
4. Patients presenting poly-trauma
5. Those whose definitive fixation is not delayed due to excessive oedema
6. Those unable to give informed consent
7. Patients on regular anti-inflammatories (e.g. taken daily for the previous 7 days)
8. On medication that precludes this procedure, e.g. anti-coagulants

Date of first enrolment

21/11/2026

Date of final enrolment

30/04/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Medefer (uhnm Royal Stoke University Hospital, Stoke-on-trent)

Newcastle Road

Stoke-on-trent

England

ST4 6QG

Sponsor information

Organisation

Keele University

ROR

<https://ror.org/00340yn33>

Funder(s)

Funder type

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available