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Ankle fracture fixation with or without a tourniquet

Submission date
02/04/2025

Recruitment status
Recruiting

Registration date
14/05/2025

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Surgery

[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
Ankle fracture fixation surgery is common. Some surgeons perform this operation with the use of a tourniquet. This is a cuff device placed around the patient's thigh during surgery. Benefits of tourniquet use may include less bleeding, better visibility, and shorter procedure time. However, tourniquets may cause pain and increase the risks of complications, e.g. infection. A definitive randomised controlled trial (RCT) is needed to compare outcomes on this topic and address clinical uncertainties. In preparation, a two-centre feasibility RCT and qualitative interviews will be carried out to improve the quality of the future trial and determine key study parameters. These include recruitment rate, reasons for non-participation, equipoise, effectiveness and views on blinding processes, protocol non-adherence, data incompleteness, and required sample size. This study aims to determine whether a full RCT evaluating outcomes of ankle fracture fixation surgery performed with or without a tourniquet is feasible.

Who can participate?
Feasibility RCT: patients over the age of 18 years undergoing primary fracture fixation surgery from either University Hospital Coventry & Warwickshire (UHCW) or Royal London Hospital (RLH). Qualitative interviews: patients over the age of 18 years undergoing primary fracture fixation surgery and Consultant Trauma & Orthopaedic Surgeons from either UHCW or RLH.

What does the study involve?
Consented RCT patients will be randomly allocated to the intervention (tourniquet to be used) or control (tourniquet not to be used). After the surgery, they will get the same care as if they hadn't joined the study, however they will be asked to fill out short questionnaires at 1 day, 3 weeks, and 3 months after the operation and will be followed up 3 months past their ankle fracture fixation surgery. Consented interview participants will take part in a 30–60-minute interview.

What are the possible benefits and risks of participating?.
There will not be any direct benefit from taking part but the participants will help to improve the quality of any future trial.
The RCT study risks are similar whether the surgery is carried out with or without a tourniquet and are the same if patients choose not to participate in this research (risks of pain, bleeding,

blood clots, damage to nerves and blood vessels, and risks related to the anaesthetic). There may be different risks depending on whether or not the tourniquet is used. Some surgeons think that using a tourniquet might cause problems such as more pain after the operation or a higher chance of wound problems, or having a blood clot. On the other hand, there may be more bleeding during the operation if a tourniquet is not used, which may make the operation more challenging for the surgeon to do.
The interview study has no anticipated risks.

Where is the study run from?
The study is run from the University of Warwick in collaboration with University Hospitals Coventry and Warwickshire's Trial Management Unit (UK)

When is the study starting and how long is it expected to run for?
March 2025 to May 2026

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

Who is the main contact?
1. Muhamed Farhan-Alanie (Research Fellow), muhamed.alanie@doctors.org.uk
2. For trial management-specific queries: Cristiana Huhulea (Trial Coordinator), cristiana.huhulea@uhcw.nhs.uk

Contact information

Type(s)
Public

Contact name
Miss Cristiana Huhulea

Contact details
Research and Development
University Hospitals Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX
+44 (0)24 7696 7476
cristiana.huhulea@uhcw.nhs.uk

Type(s)
Principal investigator

Contact name
Mr Muhamed Farhan-Alanie

Contact details
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Road

Coventry
United Kingdom
CV4 7AL
+44 (0)7503237036
muhamed.alanie@doctors.org.uk

Type(s)
Scientific

Contact name
Prof Julie Bruce

Contact details
Warwick Clinical Trials Unit
University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL
Not available
julie.bruce@warwick.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
331292

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SOC.05/24-25, CPMS 67205

Study information

Scientific Title
Tourniquet use in ankle fracture fixation surgery: a feasibility randomised controlled trial

Acronym
AFFixT

Study objectives
To determine the feasibility of conducting a randomised controlled trial examining the benefits and risks of using a tourniquet in ankle fracture fixation surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/05/2025, East of England - Essex Research Ethics Committee (2 Redman Place, London, EC20 1 JQ, United Kingdom; +44 (0)207 104 8106; Essex.REC@hra.nhs.uk), ref: 25/EE/0051

Study design
Feasibility randomized controlled trial and integrated qualitative interview study

Primary study design
Interventional

Study type(s)
Treatment, Other

Health condition(s) or problem(s) studied
Primary fracture fixation surgery

Interventions
This is a multi-centre feasibility RCT recruiting ankle fracture patients from University Hospitals Coventry and Warwickshire and Royal London Hospital with an embedded qualitative element (interviews) for both patients and staff. Consented RCT patients will be randomised 1:1 by block randomisation to the intervention (tourniquet to be used) or control (tourniquet not to be used) and will be followed-up 3 months past their ankle fracture fixation surgery. Patients and surgeons will be blinded to the randomization allocation.

The embedded qualitative interviews will be conducted with both patients and consultant trauma and orthopaedic surgeons who participated or declined to participate in the feasibility randomised controlled trial.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
1. Recruitment rates measured throughout the recruitment period using a study site tracker
2. Retention rates will be assessed at the end of the study by comparing the number of participants recruited and those who have completed the study
3. Data completeness will be assessed periodically using reports from the database
4. Blinding feasibility will be assessed based on reports of unblinding (up to 3 months post patient ankle fracture fixation) and explored during the surgeon qualitative interviews
5. Intervention adherence will be measured throughout the study recruitment and follow-up period, based on reported protocol deviations/violations

Key secondary outcome(s))

1. Post-operative pain measured at baseline, 24 hours, 3 weeks and 3 months post-operatively using the painDETECT questionnaire and 11-point pain Numerical Rating Scale
2. Surgical field of view measured on the day of the procedure using a 5-point Likert scale
3. Blood loss and blood transfusions measured on the day of the procedure and up to 2 weeks post-procedure by measuring the weight of the surgical swabs, volume of blood collected and number of intraoperative and post-operative blood transfusions
4. Length of procedure measured on the day of the procedure
5. Skin assessment will be assessed pre-operatively and on the day of the procedure and collected from medical notes
6. Awareness of tourniquet use will be measured post-operatively using a self-completed questionnaire
7. Health-related quality of life will be measured at baseline, 3 weeks and 3 months post-operatively using a modified EQ5D5L questionnaire
8. Functional recovery after the ankle injury will be assessed using the Olerud-Molander Ankle Score at baseline, 3 weeks and 3 months post-operatively
9. Post-operative complications measured 3 months post-procedure will be captured using a patient self-reported questionnaire
10. Intra-operative complications will be captured on the day of the procedure through a surgeon-completed questionnaire

Completion date
31/05/2026

Eligibility

Key inclusion criteria
Feasibility RCT:
1. Aged 18 years and over
2. Patients undergoing primary fracture fixation surgery for a closed ankle fracture within 2 weeks of date of injury under general and/or regional anaesthetic
3. Capacity to give informed consent

Embedded Qualitative Interview Study:
1. Aged 18 years and over
2.1. Consultant Trauma & Orthopaedic Surgeons who participated or declined to participate in the feasibility randomised controlled trial
OR
2.2. Patients who participated or declined to participate in the feasibility randomised controlled trial
3. Ability to provide informed consent

Participant type(s)
Health professional, Patient

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
Feasibility RCT:
1. Patients with a pilon fracture
2. Unable to understand and speak English (or does not have relative willing to translate)
3. Patients with a chronic musculoskeletal or neurological condition (excluding diabetes mellitus) affecting the operative limb, or a history of prior surgery on the affected limb

Embedded Qualitative Interview Study:
1. Unable to understand and speak English (or does not have relative willing to translate)

Date of first enrolment
19/06/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street

London
England
E1 2ES

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

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

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from the chief investigator, Prof. Julie Bruce (Julie.Bruce@warwick.ac.uk) or clinical research fellow, Mr. Muhamed Farhan-Alanie (muhamed.farhan-alanie@nhs.net) by written application that will need to also be approved by the sponsor. Only anonymised data will be shared with external researchers. Consent from participants is being obtained to allow the researchers to share their data anonymously.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes