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Ankle fracture imaging of patients with a complex injury

Submission date
16/05/2024

Recruitment status
Recruiting

Registration date
20/08/2024

Overall study status
Ongoing

Last Edited
01/09/2025

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
Every day in the UK around 170 people have an ankle fracture, and the numbers are increasing by about 10% each year. A complex ankle fracture involves a break of two, or more, bones and usually requires an operation. Everyone has an X-ray of their ankle if they have a fracture, but some surgeons will also want a Computed Tomography (CT) scan to show more cross sectional detail of the injury. Although there is some evidence that a CT scan can help in making treatment decisions, no research has examined how quickly this should occur and it is unclear whether this delays treatment. We want to find out if doing an early CT scan could speed up treatment decisions and improve recovery (outcomes).

This small research project, which aims to recruit a minimum of 60 patients in a single hospital Trust, will help us to work out if it is feasible to do a larger project across multiple hospitals in the future. The primary aim at this stage is therefore to establish the criteria required (patient outcomes, population, recruitment) for a larger trial.

Who can participate?
Adult patients aged 16 years and older, attending the emergency department or urgent treatment centre with a radiographically confirmed unstable or complex ankle fracture. Participants are eligible if the trial intervention (early CT scan) can be provided within 24 hours of presentation at hospital. They must have no other significant injuries or complications, be able to provide consent and adhere to questionnaire completion.

What does the study involve?
Participants are consenting to the recording of routinely collected information about their emergency department visit, imaging investigations and definitive treatment. A questionnaire at baseline will establish their pain and mobility before and after the injury.

Participants will be randomly allocated to a control group or intervention group so that there is at least 30 people in each group. The imaging tests carried out in the control group (post initial diagnosis with X-ray) will be at the discretion of the consultant orthopaedic surgeon, this may include a CT scan for pre-treatment planning. Those in the intervention group will be booked for a CT scan on the same or next day as part of an early cross-sectional imaging strategy. The

treatment and clinical follow up of all participants will be in line with the usual care provided by the Trust.

After discharge from hospital, participants will be followed up for 6 months after the injury using questionnaires to map measures for ankle function and quality of life, as well as NHS resource use and complications. A small sub-set of participants in both groups will contribute to qualitative interviews around the lived experience of their injury, the imaging tests performed and participation in the research.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part in the study, but the results will help to ensure that those who injure their ankle after the study is completed will have a clear imaging pathway for fracture diagnosis and treatment planning.

There are no expected risks from taking part in this study if allocated to the control group as all imaging examinations are standard care. Those in the interventional group will all have a CT scan, that may, or may not have been obtained if not participating in the study. There is an extremely small risk associated with this radiation burden which will be explained as part of the study consent procedure.

Follow up telephone calls to complete questionnaires will be kept as short as possible and conducted at a convenient time.

Where is the study run from?
The Mid Yorkshire Teaching NHS Trust, Pinderfields Hospital, UK.

When is the study starting and how long is it expected to run for?
March 2024 to August 2026

Who is funding the study?
The College of Radiographers Industry Partnership Scheme (CoRIPS award 202) (UK)

Who is the main contact?
Martine Mallinson, PhD; Chief Investigator & Lead Research Radiographer, martine.harris@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323665

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 323665, CPMS 62762

Study information

Scientific Title
Ankle fracture imaging: a feasibility randomised controlled trial examining the impact of early CT on outcomes of patients with a complex injury

Acronym
ALIGN

Study objectives
The British Orthopaedic Association (BOA) recommend that surgery for a complex ankle fracture should be performed within 24 hours. A growing evidence base suggests that CT scans provide additional clinical information for treatment planning. However, research is required to confirm if early CT scanning is valuable and results in improved outcomes for patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/10/2024, Yorkshire & The Humber- South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre , Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8021; southyorks.rec@hra.nhs.uk), ref: 24/YH/0190

Study design
Single-centre feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied
Complex and/or unstable ankle fracture

Interventions
Participants with a radiographically confirmed complex ankle fracture will be allocated 1:1 to a standard care arm where any imaging will be performed at the discretion of the Consultant Orthopaedic Surgeon, or to an intervention arm where a CT scan will performed on all participants on day 0-1 after the injury.
Participants will be randomised using the online web service sealedenvelope.com.

Intervention Type
Other

Primary outcome(s)
Ankle symptoms measured using the Olerud- Molander Ankle Score (OMAS) at 6 months after the injury

Key secondary outcome(s))
1. Ankle symptoms measured using the Olerud- Molander Ankle Score (OMAS) at 6 weeks, 3 months and 6 months after the injury
2. Health related quality of life measured using the EQ-5D-5L questionnaire at 6 weeks, 3 months and 6 months after the injury
3. Healthcare resource use measured using patient questionnaire and routine hospital attendance data of planned and unplanned visits to hospital at study allocation, 6 weeks, 3 months and 6 months after the injury
4. Feasibility measured using screening and recruitment logs, and change of status forms (Withdrawals, loss to follow up) at study close out
5. Patient experience measured using semi structured qualitative interviews to explore the lived experience of a sub-set of participants in both study arms at 6 weeks and 6 months post allocation

Completion date
13/08/2026

Eligibility

Key inclusion criteria
1. Adult patients aged 16 years and over
2. Radiographic evidence of a complex and/or unstable ankle fracture
3. The trial intervention (CT scan) can be provided within 24 hours of presentation
4. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. The injury is more than 24 hours old
2. The patient is younger than 16 years old or they are pregnant
3. There are bilateral or additional fractures, or involvement of other body systems where treatment and rehabilitation would vary from normal expected procedures, and outcomes for the trial may be affected
4. Cases of open fracture with severe soft tissue compromise giving rise to additional complications affecting trial outcomes
5. Definitive emergent treatment has occurred or has been initiated
6. The patient would be unable to adhere to trial procedures or complete questionnaires

Date of first enrolment
20/02/2025

Date of final enrolment
13/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Sponsor information

Organisation
Mid Yorkshire Hospitals NHS Trust

ROR
https://ror.org/05g23q746

Funder(s)

Funder type
Charity

Funder Name
College of Radiographers

Alternative Name(s)
CoR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

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

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