

Ankle fracture imaging of patients with a complex injury

Submission date 16/05/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/09/2025	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

323665

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

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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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

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

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 be 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 measure

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

Secondary outcome measures

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

Overall study start date

04/03/2024

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

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

60

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**

England

United Kingdom

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

Sponsor details

Pinderfields Hospital
Aberford Road
Wakefield
England
United Kingdom
WF1 4DG
+44 (0)1924 543319
Alex.clarkson1@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.midyorks.nhs.uk/>

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

Publication and dissemination plan

The findings will be shared through traditional and novel methods. Traditional dissemination of key outputs with the academic and clinical community will be through an international conference presentation and a professional peer-review publication, focussing on stakeholders including radiology, emergency medicine and trauma and orthopaedics. Links will be developed with key organisations such as the British Orthopaedic Association and NICE as the outcomes will be of interest to these bodies and their networks. Open access is not being considered within the dissemination of this small-scale feasibility study but will be for a future prospective multicentre RCT exploring the wider impact of CT within the ankle fracture pathway.

Study participants will be consented to receive a summary of the research outcomes. With support from the local NHS communications team, the results of the study will be shared with patients, the public and staff through a plain English summary and infographic. To ensure that the results are accessible to a wide audience, professional and public dissemination will also include a range of social media reporting including X (formerly known as Twitter) and other relevant charities, patient associations and blogs.

Intention to publish date

28/08/2026

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