

# In younger adults with unstable ankle fractures treated with close contact casting, is ankle function not worse than those treated with surgical intervention?

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<b>Registration date</b> 01/10/2019	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 06/12/2024	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Ankle fracture is one of the most common UK musculoskeletal injuries. Routinely, unstable fractures are treated with surgery to maintain the joint alignment whilst the fracture heals. However, for patients who experience complications after surgery, their loss of ankle function and quality of life is considerable. An alternative, non-surgical treatment is to apply a close contact cast (CCC); a plaster cast carefully shaped to the patient's ankle to correct and maintain alignment of the joint. The key benefit of CCC is a reduced risk of the complications of surgery. The main potential risk of CCC is a loss of joint alignment with a consequent reduction in ankle function. CCC is a current evidence-based treatment in the UK for patients over 60.

This study aims to determine whether ankle function four months after treatment in younger adult patients with unstable ankle fractures treated with CCC is not worse than those treated with surgery, which is the current standard-of-care.

### Who can participate?

Adult patients aged up to 60 with unstable ankle fractures

### What does the study involve?

Participants will be randomised to receive either surgical or non-surgical treatment. All treatments will be delivered under the supervision of a consultant trauma and orthopaedic surgeon. Data regarding ankle function, quality-of-life, complications and costs will be collected at eight weeks, four and twelve months and then annually for five years following treatment.

### What are the possible benefits and risks of participating?

The risks of the injury itself are the same for both groups of patients in the study, and are the same as for patients who are not taking part in the trial. Both treatments are used across the NHS currently and are not new or experimental. There is a small risk of complications if patients have the operation, such as infection and prominent metalwork, as with any surgery. We expect

that some patients will need to return for a further operation. The specific risks of surgery would not apply with the close contact cast. The main potential risk of the cast treatment is that the bones move out of place, which may require further treatment, and that might be an operation. It is also possible that while patients are under anaesthetic, the surgeon decides he or she cannot hold your bones into the right position satisfactorily with the cast, and the patient would then receive an operation straight away.

Where is the study run from?  
John Radcliffe Hospital, Oxford, UK

When is the study starting and how long is it expected to run for?  
October 2019 to September 2028

Who is funding the study?  
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Who is the main contact?  
Mrs Anju Chalin  
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## Contact information

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Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

CPMS 42891

## Study information

### Scientific Title

In younger adults with unstable ankle fractures treated with close contact casting, is ankle function not worse than those treated with surgical intervention? The Fractured Ankle Management Evaluation (FAME) trial

### Acronym

FAME

### Study objectives

Ankle fracture is one of the most common UK musculoskeletal injuries. Routinely, unstable fractures are treated with surgery to maintain the joint alignment whilst the fracture heals. However, for patients who experience complications after surgery, their loss of ankle function and quality-of-life is considerable. An alternative, non-surgical treatment is to apply a close contact cast (CCC); a plaster cast carefully shaped to the patient's ankle to correct and maintain alignment of the joint. The key benefit of CCC is a reduced risk of the complications of surgery. The main potential risk of CCC is a loss of joint alignment with a consequent reduction in ankle function. CCC is a current evidence-based treatment in the UK for patients over 60.

This study aims to determine whether ankle function four months after treatment in younger adult patients with unstable ankle fractures treated with CCC is not worse than those treated with surgery, which is the current standard-of-care.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 03/09/2019, NHS HRA Leicester Central (Devonshire Place, 78 London Road, Leicester, LE2 0RA; +44 (0)207 1048107; NRESCommittee.EastMidlands-LeicesterCentral@nhs.net), ref: 19/EM/0264

### Study design

Randomized; Interventional; Design type: Treatment, Surgery

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Unstable ankle fractures

## **Interventions**

This trial is a pragmatic, multicentre, randomised non-inferiority clinical trial with parallel economic analysis, with direct participant follow-up to one year, and annual surveillance extending out to five years. Patients will be randomised to either surgery or close contact casting for treatment of their ankle injury; the randomisation will be on a 1:1 basis, stratified by centre and the presence or absence of posterior malleolus fracture, a specific indicator of instability. If noninferiority is demonstrated, superiority will also be investigated.

In a 9-month pilot, we expect to open 9 sites and obtain a recruitment rate of at least 1 participant per centre per month. At the end of this pilot, the Data Safety and Management Committee will make recommendations to the Trial Steering Committee (TSC), as to whether the trial should continue. The TSC will evaluate this information and make a decision based on this and other information that they require for a decision.

In the study as a whole, a total of 890 participants will be recruited in a minimum of 26 hospital orthopaedic or trauma departments within the UK. A member of the research team at the site will screen patients for eligibility, and when this is confirmed by a clinician, a GCP-trained member of the team will approach the patient to explain the study and gain informed consent. Participants will complete questionnaires at baseline, and site staff will complete a treatment questionnaire at the participant's 6-week clinic visit. Participants will complete follow-up questionnaires at 8 weeks, 4 months and 12 months after treatment, thereafter they will be contacted annually for a further 4 years. We will also collect routine hospital data through a linkage with Hospital Episode Statistics (inpatient and emergency department datasets).

Data will be collected via the clinical trial IT system REDCap, hosted by the University of Oxford, UK. Baseline data will be directly entered onto the database by the local research team. Participants will be contacted for follow-up using email and/or SMS text message prompts and invited to complete questionnaires through an online link, and telephone follow-up will be conducted for those who do not complete forms online.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Current primary outcome measure as of 16/12/2020:

Ankle functional outcomes measured by the Olerud and Molander ankle score (OMAS) at 4 months.

Previous primary outcome measure:

Ankle functional outcomes measured by the Olerud and Molander ankle score (OMAS) at baseline and 4 months.

**Key secondary outcome(s)**

1. OMAS at 8 weeks and 12 months
2. A-FORM (a specific ankle fracture questionnaire) at 8 weeks, 4 months and 12 months
3. Work Productivity and Activity Impairment (WPAI) at 8 weeks, 4 months and 12 months
4. Health-related quality of Life (EQ-5D-5L) at 8 weeks, 4 months and 12 months
5. Resource use, costs and comparative cost-effectiveness at 8 weeks, 4 months and 12 months and up to 5 years
6. OMAS, A-FORM, EQ-5D-5L and complications at all timepoints up to 5 years

**Completion date**

05/09/2028

**Eligibility****Key inclusion criteria**

1. Patients who are able and willing to give informed consent for participation in the trial
2. Patients aged 18 to 60 years inclusive with an unstable ankle fracture
3. Patients who in the opinion of the treating surgeon may benefit from surgical treatment with internal fixation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

60 years

**Sex**

All

**Total final enrolment**

891

**Key exclusion criteria**

1. The fracture is open
2. The fracture is complicated by local tumour deposits
3. The injury is an isolated fracture of the medial malleolus
4. The index injury occurred more than 14 days prior to recruitment
5. They are unable to adhere to trial procedures
6. Previous randomisation in the current trial

**Date of first enrolment**

01/10/2019

**Date of final enrolment**

05/09/2023

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

**Study participating centre**

**University Hospitals Bristol NHS Foundation Trust**

Marlborough Street

Bristol

United Kingdom

BS1 3NU

**Study participating centre**

**Southport and Ormskirk Hospital NHS Trust**

Town Lane

Southport

United Kingdom

PR8 6PN

**Study participating centre**

**Barts Health NHS Trust**

The Royal London Hospital

Whitechapel

London  
United Kingdom  
E1 1BB

**Study participating centre**  
**South Tees Hospitals NHS Foundation Trust**  
James Cook University Hospital  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**Epsom and St Helier University Hospitals NHS Trust**  
St Helier Hospital  
Wrythe Lane  
Carshalton  
Surrey  
United Kingdom  
SM5 1AA

**Study participating centre**  
**Milton Keynes University Hospital NHS Foundation Trust**  
Milton Keynes University Hospital  
Standing Way  
Milton Keynes  
United Kingdom  
MK6 5LD

**Study participating centre**  
**Northumbria Specialist Emergency Care Hospital**  
Northumbria Way  
Cramlington  
Northumberland  
United Kingdom  
NE23 6NZ

**Study participating centre**  
**Taunton and Somerset NHS Foundation Trust**  
Musgrove Park Hospital  
Parkfield Drive

Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**  
**Oxford University Hospitals NHS Foundation Trust**  
Horton General Hospital  
Oxford Road  
Banbury  
United Kingdom  
OX16 9AL

**Study participating centre**  
**City Hospitals Sunderland NHS Foundation Trust**  
Sunderland Royal Hospital  
Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Kettering General Hospital**  
Rothwell Road  
Kettering  
United Kingdom  
NN16 8UZ

**Study participating centre**  
**Doncaster Royal Infirmary**  
West Block  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**  
**Medway Maritime Hospital**  
Windmill Road  
Gillingham  
United Kingdom  
ME7 5NY

**Study participating centre**  
**Royal Victoria Infirmary**  
Newcastle upon Tyne  
United Kingdom  
NE1 4LP

**Study participating centre**  
**NHS Fife**  
Queen Margaret Hospital  
Whitefield Road  
Dunfermline  
Fife  
United Kingdom  
KY12 0SU

**Study participating centre**  
**St Mary's Hospital**  
Newport, Isle of Wight  
United Kingdom  
PO30 5TG

**Study participating centre**  
**Forth Valley Royal Hospital**  
Stirling Road  
Larbert  
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FK5 4WR

## **Sponsor information**

**Organisation**  
University of Oxford

**ROR**  
<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR127273

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Xavier Griffin (x.griffin@qmul.ac.uk). Requests can be made 3 years after the publication of the main trial results. The data would be anonymised. The exact details of the type of data, for what type of analyses and for how long will be determined on a case-by-case basis.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>		07/03/2024	06/12/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes