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

Submission date
23/09/2019

Recruitment status
No longer recruiting

Registration date
01/10/2019

Overall study status
Ongoing

Last Edited
06/12/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] 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 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
anju.chalin@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Anju Chalin

Contact details
Research Office 3
Kadoorie Centre, Level 3
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223123
anju.chalin@ndorms.ox.ac.uk

Type(s)
Scientific

Contact name
Dr Susan Wagland

Contact details
Oxford Trauma Kadoorie Centre
Level 3 John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom

OX3 9DU
+44 (0)1865 223123
fame@ndorms.ox.ac.uk

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
United Kingdom
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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		07/03/2024	06/12/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes