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Weight-bearing in ankle fractures

Submission date
02/12/2019

Recruitment status
No longer recruiting

Registration date
10/12/2019

Overall study status
Completed

Last Edited
11/06/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are around 170 ankle fractures each day in the UK. Many of these injuries heal with support in a plaster cast or splint, but some require surgery to restore the natural alignment of the bones and fix them in place with screws and plates. This improves how the ankle works once the fracture has healed. Following surgery for an ankle fracture, patients are commonly told not to walk on the affected leg for 6 weeks in order to allow the bones to heal. Restricting the weight put through the affected leg may reduce the chance of surgical complications such as infection, breakage of the plates and screws, and loss of alignment requiring revision surgery. However, this restriction has been associated with problems such as blood clots, muscle weakness, stiffness, and poor recovery. It is unclear that the traditional 6 weeks period of limited walking is of any benefit. A recent national review found that surgeons gave patients very varied instructions following ankle fracture surgery, indicating that overall, UK surgeons have differing opinions about the best extended treatment pathway. There has been little high-quality research in this area.

This study is asking should patients who have had surgery for an ankle fracture walk on their operated leg soon following surgery or wait 6 weeks before walking on the operated leg. It is a clinical trial, which is the best method to compare treatments to guide the care of patients.

Who can participate?
This study will include adults (aged 18 years or above) undergoing surgery for an ankle fracture.

What does the study involve?
All patients will be treated non-weight-bearing until their 2-week postoperative follow-up visit. They will then be instructed to either begin weight-bearing on the injured leg, or remain non-weight-bearing for an additional 4 weeks. The decision on which instruction they are given will be made by chance using a process called randomisation so that neither patients nor surgeons can influence the choice. All other care will be as per usual treatment. Patients will report how well their ankle is working and their quality of life using questionnaires at intervals over the first year following surgery. Differences in healthcare costs will also be compared. A small sample of patients and staff will also be interviewed to discuss their experience of the trial. These interviews will help understand how and why the different treatments may work and help design future studies.

What are the possible benefits and risks of participating?
Early weight-bearing, from two weeks after the operation, may reduce the inconvenience of having to use crutches and reduce immobility, length of hospital stay, and might lead to improved ability to walk, get back to work etc.. However, there is a small chance that putting weight through the ankle at an early stage may lead to the bone moving slightly or the skin around the injury and the incision made for the operation being damaged or causing infection, which might mean further treatment, such as an operation, is required.

Delayed weight-bearing, for up to 6 weeks after the operation, may reduce the risk of the bones slipping out of place, the skin around the injury being damaged and as such a need for further operations. However, it will be more inconvenient and it could lead to increased time off work and other activities. Participants will not be using the calf muscle and might lose some muscle mass and this means it might take longer after the initial 6 weeks to return to usual strength and activities. Finally, although highly unlikely, there may be a slightly increased chance of getting a blood clot in the calf or lung, which could require additional blood-thinning medication.

Where is the study run from?
The University of Oxford, UK

When is the study starting and how long is it expected to run for?
December 2019 to November 2022

Who is funding the study?
Research for Patient Benefit Programme, National Institute for Health Research (NIHR), UK

Who is the main contact?
1. Dr Susan Wagland (public), wax@ndorms.ox.ac.uk
2. Mr Chris Bretherton (scientific), christopher.bretherton@ndorms.ox.ac.uk

Study website
http://wax.octru.ox.ac.uk/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
265559

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43740, IRAS 265559

Study information

Scientific Title
Weight Bearing in Ankle Fractures. A randomised clinical trial of weight-bearing following operatively treated ankle fracture

Acronym
WAX

Study objectives
Weight bearing at 2 weeks is not inferior to weight bearing at 6 weeks after surgically repaired unstable ankle fracture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/12/2019, South Central- Oxford A- Health Research Authority (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8041; nrescommittee.southcentral-oxforda@nhs.net), ref: 19/SC/0566

Study design
Multi-centre prospective randomised non-inferiority clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Surgically repaired unstable ankle fractures

Interventions
Early-weight bearing vs Delayed weight-bearing.

Initially patients will be instructed to be non-weight bearing in the immediate two weeks following surgery, as per usual clinical care, to allow the soft tissues to recover and wounds to heal. At two weeks, participants will be randomised (online using RRAMP) in a 1:1 ratio stratified by centre and whether they are aged under 60 or 60 and over, to either early weight-bearing (unrestricted weight-bearing group, begin weight-bearing immediately at 2 weeks after their operation) or to delayed weight-bearing (restricted weight-bearing group, wait until 6 weeks after the operation) for a period of four weeks. Participants will be given verbal and standardised written instructions dependant on their randomisation outcome. Both of these weight-bearing strategies are widely used within the NHS and all of the clinical teams in the chosen centres will be familiar with both instructions. At four weeks post-randomisation participants' weight-bearing status will default back to routine clinical care. Patients will be followed up for four months.

Baseline demographic data and pre-injury functional data using the OMAS instrument will be collected. Participants will also be asked to complete the EuroQol EQ-5D-5L health-related quality-of-life questionnaire to indicate their typical pre-injury health status. At 4 weeks post-randomisation, the clinical team will perform a clinical assessment; participants will be asked to complete the OMAS and a record of any early adverse events made. Additionally, OMAS, EQ-5D-

5L, Global rating of change (GRC), Pain self-efficacy questionnaire and Tampa scale of kinesphobia-11, adverse events and resource use questionnaires will be collected at 6 weeks, 4 and 12 months post randomisation.

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, postal and telephone follow-up will be conducted for those who are not comfortable to, or cannot complete forms online.

A process evaluation will be performed. The main aim of this evaluation will be to identify barriers and facilitators in the delivery of the interventions, look for selection and researcher bias and to understand the generalizability of the trial, through a mixed methods approach. This will include qualitative interviews with staff and participants as well as a quantitative assessment of the characteristics of the sample and fidelity of the interventions. The interviews will be conducted by a student researcher (after sufficient training) and take place over the telephone, in clinic or hospital/university meeting rooms. Patients will be approached at the time of consent to the main trial to see if they would be happy to be contacted for the interview. Patient's who do not wish to take part in the main trial may still consent to be approached and then complete the interview. All participants completing the interview will sign a separate consent form.

Intervention Type
Behavioural

Primary outcome measure
Ankle function outcomes measured by the Olerud and Molander Score (OMAS) at the 4 month follow-up time-point

Secondary outcome measures
1. OMAS at 6 weeks and 12 months
2. Health related quality of life (EQ-5D-5L) at 6 weeks, 4 months and 12 months
3. Resource use, costs and comparative cost utility (The Work Productivity and Activity Impairment) at 6 weeks, 4 months and 12 months
4. Difference in risk of adverse events (adverse events)
5. Investigate generalisability, acceptability and mechanism of action of the trial and interventions (CRF's, patient and staff interviews) 6 weeks, 12 months

Overall study start date
01/09/2019

Completion date
18/11/2022

Eligibility

Key inclusion criteria
1. Age 18 years and above
2. The patient has undergone operative fixation for an unstable ankle fracture

3. Surgery was performed within 14 days of the injury
4. In the opinion of the treating surgeon, the participant might benefit from early weight-bearing
5. Able and willing to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
436

Total final enrolment
562

Key exclusion criteria
1. A lack of protective sensation (e.g. peripheral neuropathy)
2. Inability to adhere to trial procedures
3. Bilateral operatively treated ankle fractures
4. Already in a trial for ankle fracture
5. The patient has received a hindfoot nail to treat index fracture

Date of first enrolment
23/12/2019

Date of final enrolment
28/10/2021

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Wales

Study participating centre
Royal Berkshire Hospital
Reading

United Kingdom
RG1 5AN

Study participating centre
Salisbury District Hospital
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Tunbridge Wells Hospital
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TN2 4QJ

Study participating centre
Lewisham Hospital
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SE13 6LW

Study participating centre
Royal United Hospitals Bath
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University Hospital Coventry And Warwickshire
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United Kingdom
CV2 2DX

Study participating centre
Dorset County Hospital
Dorchester
United Kingdom
DT1 2JY

Study participating centre
Gloucestershire Royal Hospital
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Manchester Royal Infirmary
Manchester
United Kingdom
M13 9WL

Study participating centre
Princess Alexandra Hospital
Harlow
United Kingdom
CM20 1QX

Study participating centre
Princess Royal University Hospital
Orpington
United Kingdom
BR6 8ND

Study participating centre
Queen Alexandra Hospital
Portsmouth
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PO6 3LY

Study participating centre

Royal Derby Hospital
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal Preston Hospital
Preston
United Kingdom
PR2 9HT

Study participating centre
Royal Victoria Hospital
Belfast
United Kingdom
BT12 6BA

Study participating centre
Salford Royal Hospital
Salford
United Kingdom
M6 8HD

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Study participating centre
Wexham Park
Slough
United Kingdom
SL2 4HL

Study participating centre

East Surrey Hospital
Redhill
United Kingdom
RH1 5RH

Study participating centre
Basingstoke and North Hampshire Hospital
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Royal Cornwall Hospital
Truro
United Kingdom
TR1 3HD

Study participating centre
Conquest Hospital
St Leonards-on-Sea
United Kingdom
TN37 7RD

Study participating centre
University Hospital Llandough
Penarth
United Kingdom
CF64 2XX

Study participating centre
Peterborough City Hospital
Peterborough
United Kingdom
PE3 9GZ

Study participating centre

Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Craigavon Hospital
Portadown
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BT63 5QQ

Study participating centre
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Ashford
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TN24 0LZ

Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

Funder(s)

Funder type

Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
wax@ndorms.ox.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/08/2021	12/10/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		04/06/2024	11/06/2024	Yes	No