ISRCTN12883981 https://doi.org/10.1186/ISRCTN12883981

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
02/02/2026

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

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
265559

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

100 years

Sex
All

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
United Kingdom

England

Northern Ireland

Wales

Study participating centre
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
England
SP2 8BJ

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
Tunbridge Wells
England
TN2 4QJ

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
England
SE13 6LH

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
England
BA1 3NG

Study participating centre
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
England
LL57 2PW

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre

Dorset County Hospital
Williams Avenue
Dorchester
England
DT1 2JY

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Princess Alexandra Hospital
Hamstel Road
Harlow
England
CM20 1QX

Study participating centre
Princess Royal University Hospital
Farnborough Common
Orpington
England
BR6 8ND

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
England
PR2 9HT

Study participating centre
Royal Victoria Hospital
Radnor Park Avenue
Folkestone
England
CT19 5BN

Study participating centre
Salford Royal Hospital
Stott Lane
Salford
England
M6 8HD

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre

Wexham Park Hospital
Wexham Street
Wexham
Slough
England
SL2 4HL

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
England
RH1 5RH

Study participating centre
Basingstoke and North Hampshire Hospital
Aldermaston Road
Basingstoke
England
RG24 9NA

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LJ

Study participating centre
Conquest Hospital
The Ridge
St. Leonards-on-sea
England
TN37 7RD

Study participating centre
University Hospital Llandough
Penlan Road
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Penarth
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CF64 2XX

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
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England
PE3 9GZ

Study participating centre
NIHR Nottingham Biomedical Research Centre
Queens Medical Centre
Derby Road
Nottingham
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NG7 2UH

Study participating centre
Craigavon Area Hospital
Lurgan Rd
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BT63 5QQ

Study participating centre
William Harvey Hospital
Kennington Road
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Ashford
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TN24 0LZ

Sponsor information

Organisation

University of Oxford

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article		04/06/2024	11/06/2024	Yes	No
Protocol article		09/08/2021	12/10/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Co-design of rehabilitation intervention: healthcare professionals	23/01/2025	02/02/2026	Yes	No
Other publications	Co-design of rehabilitation intervention: patients	02/04/2025	02/02/2026	Yes	No

Study website	11/11/2025	11/11/2025	No	Yes