

# Weight-bearing in ankle fractures

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<b>Registration date</b> 10/12/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/02/2026	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> 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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Scientific

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## Additional identifiers

**Integrated Research Application System (IRAS)**  
265559

**Central Portfolio Management System (CPMS)**  
43740

## 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](mailto: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 kinesiophobia-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**

**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

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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

Llandough

Penarth

Wales

CF64 2XX

**Study participating centre**

**Peterborough City Hospital**

Edith Cavell Campus

Bretton Gate  
Bretton  
Peterborough  
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PE3 9GZ

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

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**Craigavon Area Hospital**  
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## **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?
<a href="#">Results article</a>		04/06/2024	11/06/2024	Yes	No
<a href="#">Protocol article</a>		09/08/2021	12/10/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Co-design of rehabilitation intervention: healthcare professionals	23/01/2025	02/02/2026	Yes	No
<a href="#">Other publications</a>	Co-design of rehabilitation intervention: patients	02/04/2025	02/02/2026	Yes	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes