ISRCTN76410775 https://doi.org/10.1186/ISRCTN76410775

Do we have to keep patients in a cast and prevent them from weight bearing after surgical repair of ankle fractures?

Submission date
20/05/2019

Recruitment status
No longer recruiting

Registration date
30/06/2019

Overall study status
Completed

Last Edited
05/08/2021

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Ankle fractures are common; usually occurring as a result of low energy torsional trauma. Generally, the treatment is either with surgical fixation or non-surgically in the form of immobilization with modified weight bearing depending on the stability of fracture and its pattern. Currently, there is a lack of consensus in post-operative management regimes in terms of the degree of mobilisation and weight bearing allowed following surgical fixation of unstable fractures about the ankle leading to a wide variation in clinical practice. There is an evolving understanding that extended periods of immobilisation and limitation of weight bearing lead to poorer outcomes.

The purpose of this study is to investigate the safety and efficacy of early weight bearing and range of motion exercise regimes after surgical fixation of unstable ankle fractures with a particular focus on functional outcomes and complication rates with an emphasis on those attributable to early weight bearing such as wound compromise and loss of fixation.

Who can participate?
All adult patients with an ankle fracture that need surgical intervention.

What does the study involve?
The proposed method of the study is to compare two groups of patient who will undergo different post-operative management programs: the control arm will be treated using a traditional process of extended immobilization in cast and limitation of weight bearing with the treatment arm being managed, after surgery, in a functional brace (walking boot) with a rehabilitation regime allowing for early exercises and weight bearing.

What are the possible benefits and risks of participating?
The researchers can't guarantee a benefit to patients who take part in this study. The results of the study may benefit future patients with similar fractures. Taking part in the study will not change the standard of care participants receive. Both modes of treatment are already routinely done in the HSE.

Where is the study run from?
In the University hospital Waterford and two other centres in Ireland awaiting final confirmation and ethical approval.

When is the study starting and how long is it expected to run for?
The study started on 07/01/2019 and expected to run until 07/07/2020

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Mr Ramy Khojaly, Orthopaedic Department, University Hospital Waterford, Waterford Ireland
wrh.ortho08@hse.ie

Contact information

Type(s)
Scientific

Contact name
Mr Ramy Khojaly

ORCID ID
https://orcid.org/0000-0002-2286-4745

Contact details
University Hospital Waterford
Dunmore Road
Waterford
Ireland
X91 CP5W
+353 51 848 000
r.e.e.khojaly@smd18.qmul.ac.uk

Additional identifiers

Protocol serial number
14-11-2018

Study information

Scientific Title
Is post-operative non-weight-bearing necessary? A pragmatic randomised multicentre trial of operatively treated ankle fracture (DoWeCAST?)

Acronym
DoWeCAST?

Study objectives

Extended periods of immobilisation and limitation of weight bearing after ankle fracture fixation is unnecessary and leads to poorer outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 14/11/2018, Research Ethics Committee Health Service Executive, South Eastern Area (Old school of nursing, University Hospital Waterford; +353 51 842026; Caroline. Lamb2@hse.ie)
2. Approved 29/10/2019, Clincial Research Ethics Committee of the Cork Teaching Hospitals (Cork University Hospital, Wilton, Cork, Ireland; +353 21 4901901; crec@ucc.ie), ref: ECM 4 (z)
3. Approved Galway University Hospitals CREC (University Hospital Galway Newcastle Rd, Galway, H91 YR71, Ireland; no tel. provided; no email provieded), ref: C.A.2248

Primary study design
Interventional

Study design
Multicentre, prospective, randomised controlled trial (RCT), un-blind with participants allocated in a 1:1 ratio to one of two parallel groups.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unstable ankle fractures

Interventions
Consent:
All patients admitted to the hospital with ankle fracture requiring surgical intervention get consented by the admitting NCHD for the ankle trail after providing appropriate information and patient information leaflet. Most of the patients get consented the night before surgery; some patients get consented in the day of surgery (day cases).

Patient's selection:
The selection process starts in the morning of surgery at the trauma meeting, the operating surgeon and one of the investigators review the patients x-rays and ensure patients are meeting the inclusion criteria, this process continues intra-operatively to ensure achievement of surgical anatomical reduction and stable internal fixation of ankle fracture.

Randomisation process:
Computer-generated block randomisation (20 patients per block) has been created at the start of the trial. Theatre nurses check the randomisation sequence by accessing the trial excel sheet and inform the surgeon with the appropriate sequence at the end of surgery and insert patients data to the sheet.

Treatment:
Patients will either get a cast or a walking boot in theatre after surgery. All patients get reviewed by a physiotherapist before discharge. Patients in the cast group are instructed to walk non-weight bearing using crutches/frame for a total of six weeks. Patients in the walking boot

group are instructed to walk weight bearing as tolerated immediately, they also instructed to remove the walking boot 4 times a day at minimum and perform ankle range of motion exercises until they referred to outpatient physiotherapy in 2 weeks. All patients receive post-operative instruction sheet.

Follow up:
Patients are followed up as following; 2 weeks, 6 weeks, 12 weeks, 6 months and 1 year. At each visit, OMAS and SF-36 Health questionnaire are collected from the patient. Attending orthopaedic consultant or NCHD fills up a case report form (Please find attached) at each visit, this includes the following information; surgical site assessment, x-ray evaluation, ankle ROM (using goniometry), information regarding return to work, confirmation of physiotherapy referral and confirmation of collection of OMAS and SF-36 Health questionnaire.

Intervention Type
Other

Primary outcome(s)
Ankle Olerud and Molander Score (OMAS) questionnaire is collected at each visit(2 weeks, 6 weeks, 12 weeks, 6 months and 1 year).

Key secondary outcome(s)
1. Ankle range of motion (plantar and dorso-flexion) is measured using goniometry at each follow-up visit.
2. Physical and mental health outcomes SF36 questionnaire are collected at each visit.
3. The time needed to return to work; patients are asked each visit if they returned to work and date of return to work is documented in the case report form.
4. Wound complication and complications related to fracture fixation and bone healing are documented at each visit.

Completion date
30/07/2021

Eligibility

Key inclusion criteria
All skeletally mature, acute ankle fractures that were treated with anatomical reduction and stable internal fixation including:
1. Isolated lateral malleolus fractures.
2. Isolated medial malleolus fractures.
3. Bi-malleolar fractures.
4.Tri-malleolar fracture.
5. Syndesmosis injuries that has been surgically fixed with either screw or tightrope.
6. Closed, grade I, or grade II open fractures.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
1. Skeletal immaturity.
2. Grade-III open fractures.
3. Tibial plafond fractures.
4. Polytrauma.
5. Non-ambulatory status before injury.
6. Expected insufficient stable fracture fixation with standard surgical technique.
7. Pre-existent cognitive disability, inability to comply with non-weight-bearing mobilization and inability to comply with follow-up.

Date of first enrolment
07/01/2019

Date of final enrolment
07/07/2020

Locations

Countries of recruitment
Ireland

Study participating centre
University Hospital Waterford
Dunmore Road, Waterford, Ireland
Waterford
Ireland
X91ER8E

Sponsor information

Organisation
University Hospital Waterford

ROR
https://ror.org/007pvy114

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/05/2021	01/06/2021	Yes	No