Prospective randomized study: early weight bearing after conservative treatment of stable ankle fractures.

Published: 06-03-2018
Last updated: 15-05-2024

Primary Objective: What are the 6-week and 12-week effects on the functional outcome scores of the ankle in early weight bearing (mobilization with Walker) compared to 6 weeks non-weight bearing and immobilization in conservatively treated stable...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON46747

Source
ToetsingOnline

Brief title
PANCAKE-trial

Condition

- Fractures

Synonym
broken ankle, stable ankle fracture

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: niet van toepassing

Intervention

Keyword: conservative treatment, early weight bearing, randomized controlled trial, stable ankle fractures

Outcome measures

Primary outcome

Functional outcome scores of the ankle. This will be indicated with the

Olerud/Molander Ankle Function Score (OMAS). This is a continuous variable

(0-100 points).

Secondary outcome

Dislocation of the fracture within 6 weeks (after placement of the Walker or

circular lower limb plaster cast). This is a dichotomous variable (yes/no).

Other study parameters

Range of motion (ROM) of the ankle and circumference of the calf (physical

examination), return to work, mental health outcome scores (SF-36

questionnaire) and other complications, such as deep vein thrombosis or

surgery.

Study description

Background summary

Ankle fractures are among the most common fractures of the lower extremities. With 9% of all fractures, they account for an important part of the traumatic injuries. A consideration between an operative vs. conservative treatment has to be made. A distinction must be made between stable and unstable ankle fractures. The fracture is stable if there is a dislocation of less than 3 millimetres at the *medial clear space* (the jointspace between the medial malleolus and the talus) with a symmetrical ankle fork on the Mortise X-ray.

Classifications are used to describe the mechanism behind the ankle fracture and thus to make a statement about the (in)stability of the ankle joint. A common type of injury is the Weber B fracture or according to the Lauge-Hansen classification the supination-eversion type, that can be stable (SE type 2 without rupture of the deltoid ligament) and also possibly unstable (SE type 4 with rupture of the deltoid ligament). This ligament has a superficial and a deep layer. The superficial layer resists plantar flexion and external rotation of the talus relative to the tibia. The deep layer has anterior and posterior components, the anterior and posterior talo-tibial ligaments (ATTL and PTTL), of which the posterior ligament is the strongest. The PTTL is tight when the foot is plantigrade and loose when the foot is plantar flexed. If however, the foot is plantigrade, as on an anteroposterior weight-bearing radiograph, the intact PTTL will prevent lateral translation of the talus and the ankle fork appears congruent. Therefore, Gougoulias N. et al. (2017) proposed that a (ligamentous) SE type 4 ankle fracture, one without a medial malleolar fracture, with a ruptured superficial and/or ATTL, but an intact PTTL, be classified as a *SE type 4A* fracture. This is a stable fracture, as long as the foot is in a plantigrade position. With a complete rupture of the superficial and deep components (both ATTL and PTTL) of the deltoid ligament, the medial clear space will open in all positions of the foot, thus also on weight-bearing radiographs. This type of fracture can be classified as SE type 4B, which is always an unstable fracture.

There is controversy about the optimal conservative treatment of common stable ankle fractures. This is confirmed by the presence of a large number of treatment protocols with great variability in weight bearing recommendations. The current international guideline describes non-weight bearing and immobilization with a plaster cast for 6 weeks. However, a prolonged period of immobilization causes various negative effects regarding recovery:
- Patient compliance: The noncompliance rate with the postoperative weight bearing restriction is almost 30% and they start with weight bearing despite explicit instructions. However, this rarely leads to displacement of the fracture. The advice currently being applied may therefore be too cautious.
- Physiological cost: Non-weight bearing with 2 elbow crutches and only 1 leg on the ground costs 4 times more energy than walking with 2 legs on the ground and 2 crutches for support or stabilization.
- Homeostasis: Weight bearing ensures the preservation of bone and muscle mass. A few weeks of non-weight bearing results in a significant decrease in bone mass in the affected extremity even a year later.
- Risk of thrombosis: Posttraumatic immobilization with a plaster cast is a risk factor for developing a deep venous thrombosis or a pulmonary embolism. At Zuyderland Medical Center, patients receive thromboprophylaxis during long term immobilization, according to protocol.
Therefore, advising non-weight bearing out of caution or uncertainty can cause harmful effects on the health of patients. However, the literature provides no substantiation for this period of non-weightbearing. When transmitting anxiety to patients, this can make them insecure, which does not contribute to

rehabilitation.

Study objective

Primary Objective: What are the 6-week and 12-week effects on the functional outcome scores of the ankle in early weight bearing (mobilization with Walker) compared to 6 weeks non-weight bearing and immobilization in conservatively treated stable ankle fractures (Weber B or Lauge Hansen supination-eversion stage 2-4A)?

Secondary Objective: What is the 6-week effect on dislocation of the fracture in early weight bearing (mobilization with Walker) compared to 6 weeks non-weight bearing and immobilization in conservatively treated stable ankle fractures (Weber B or Lauge Hansen supination-eversion stage 2-4A)?

Other Objectives: Other outcome measures include range of motion (ROM) of the ankle circumference of the calf, return to work, mental health outcome scores and rates of other complications.

Hypothesis 1: We expect earlier functional outcomes in the intervention group than in the control group.
Hypothesis 2: We expect the number of complications not to be higher in the intervention group than in the control group.
Hypothesis 3: We expect the long-term recovery function (3 months) in the intervention group not to be worse than in the control group.

Null hypothesis 1: The treatment in the intervention group is not as effective as the treatment in the control group, because there are worse functional outcomes in the intervention group than in the control group.
Null hypothesis 2: The treatment in the intervention group is not as safe as the treatment in the control group, because there are more dislocations of the fractures reported in the intervention group than in the control group.

Study design

A prospective randomized controlled trial at the Zuyderland Medical Center. We will include patients at both locations, Heerlen and Sittard/Geleen.
All patients with ankle fractures at the emergency department of both locations of the Zuyderland Medical Center are treated with a dorsal lower limb cast. 7 to 10 days posttraumatic, they are seen again at the traumatology department, according to protocol.
During this visit (= t1), radiographs of the ankle joint are obtained at 3 different views (anteroposterior (AP), lateral and Mortise) and a weight-bearing radiograph (AP). When it*s a stable fracture according to the surgeon, present at that time, the patients will be approached to participate in this randomized study. If written informed consent is obtained, the patients

get included.

Intervention

Intervention group
The dorsal lower limb cast will be removed by the plaster technician. Patients will get a Walker by which they can start with permissive weight bearing. According to protocol, they receive daily thromboprophylaxis (Fragmin 5000IE s.c.). After 6 weeks posttraumatic, the Walker will be removed at the traumatology department. The patients may then extend the weight bearing to functional.

Control group
The dorsal lower limb cast will be removed by the plaster technician and a circular lower limb plaster cast will be applied. Patients get explicit instruction of non-weight bearing and immobilization till the next visit. According to protocol, they receive daily thromboprophylaxis (Fragmin 5000IE s.c.). After 6 weeks posttraumatic, the plaster cast will be removed at the traumatology department. The patients may then start weight bearing to their own abilities.

Study burden and risks

3 site visits during 12 weeks with physical examinations and 2 questionnaires which have to be filled in during each visit. Risks of the investigational treatment are myalgia and dislocation of the fracture.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age of 16 years and older.
- Stable ankle fracture (non-dislocated Weber B or Lauge Hansen supination-eversion stage 2-4A fracture, isolated malleolus tertius fracture)
- Conversative treatment with a belowknee plaster cast.

Exclusion criteria

- Age below 16 years.
- Weber A ankle fracture.
- Unstable ankle fracture.
- Fractures involving both lower extremities.
- Operative treatment of the ankle fracture.
- Posttraumatic period more than 10 days.
- Amputation of upper leg, lower leg or foot.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2018
Enrollment:	284
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2018
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	03-04-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-06-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	03-07-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	31-07-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO	

Date:	09-12-2019
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24230
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64265.096.17
OMON	NL-OMON24230