

# Vroegtijdig belasten na niet-geopereerde botbreuk van de enkel

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24230

### Source

NTR

### Brief title

PANCAKE

### Health condition

Nederlands: Weber B, Lauge Hansen, enkelfracturen, conservatief, RCT, vroegtijdig belasten, onderbeensgips

English: Weber B, Lauge Hansen, ankle fractures, conservative treatment, RCT, randomized controlled trial, early weight bearing, plaster cast

## Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum

**Source(s) of monetary or material Support:** not applicable

## Intervention

## Outcome measures

### Primary outcome

Functional outcome score of the ankle

## Secondary outcome

Dislocation of the fracture

## Study description

### Background summary

#### SUMMARY PANCAKE TRIAL

**Rationale:** There is controversy about the optimal conservative treatment of common stable ankle fractures (Weber B or Lauge-Hansen supination-eversion stage 2-4A). The current international guideline describes non-weight bearing and immobilization with a plaster cast for 6 weeks. However, the literature provides no substantiation for this period of non-weight bearing.

**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.

**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)?

**Study design:** A prospective randomized controlled trial at the Zuyderland Medical Center. We will include patients at both locations, Heerlen and Sittard/Geleen.

**Study population:** Men and women, 16 years or older, with Weber B ankle fractures treated with a dorsal lower limb cast at the emergency department of both locations of the Zuyderland Medical Center, Heerlen and Sittard/Geleen, The Netherlands.

**Intervention:** One group will get a Walker by which they can start with permissive weight bearing. The other group will get a circular lower limb plaster cast and instructions of non-weight bearing and immobilization till the next visit. After 6 weeks, the Walker or plaster cast will be removed. The patients may then extend the weight bearing to functional.

**Main study parameters/endpoints:** The primary parameter in this study is functional

outcome score of the ankle. Secondary parameter is dislocation of the fracture. Other parameters are range of motion of the ankle, circumference of the calf, return to work, satisfaction of the patient and other complications, such as deep vein thrombosis or surgery. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

## **Study objective**

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.

## **Study design**

T1 (= baseline): 7-10 days posttrauma

T2: 6 weeks posttrauma

T3: 12 weeks posttrauma

## **Intervention**

One group will get a Walker by which they can start with permissive weight bearing. The other group will get a circular lower limb plaster cast and instructions of non-weight bearing and immobilization till the next visit. After 6 weeks, the Walker or plaster cast will be removed. The patients may then extend the weight bearing to functional.

## **Contacts**

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## Eligibility criteria

### 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).
- Conservative treatment with a dorsal lower limb 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)
Control:	Active

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 09-04-2018  
Enrollment: 142  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 04-04-2018  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 46747  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL6955
NTR-old	NTR7143
CCMO	NL64265.096.17
OMON	NL-OMON46747

## Study results