Vroegtijdig belasten na niet-geopereerde botbreuk van de enkel

Gepubliceerd: 04-04-2018 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24230

Bron
NTR

Verkorte titel
PANCAKE

Aandoening

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

Ondersteuning

Primaire sponsor: Zuyderland Medisch Centrum
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Functional outcome score of the ankle

Toelichting onderzoek

Achtergrond van het onderzoek

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 an 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.

Doel van het onderzoek

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.

Onderzoeksopzet

T1 (= baseline): 7-10 days posttrauma

T2: 6 weeks posttrauma

T3: 12 weeks posttrauma

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-04-2018
Aantal proefpersonen:	142
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46747
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten