The WOW! Study. Weight-bearing or Non-weight bearing.

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The hypothesis of this study is that direct weight-bearing after operative fixation of ankle fractures, will shorten the period of assumption to work and/or sports and improve the range of motion of the affected ankle.

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

Samenvatting

ID

NL-OMON22736

Bron
Nationaal Trial Register

Verkorte titel
WOW

Aandoening

ankle fracture, enkel fractuur
weight bearing, belaste mobilisatie
non weight-bearing, onbelaste mobilisatie

Ondersteuning

Primaire sponsor: Sint Antonius Hospital, Nieuwegein
Overige ondersteuning: self-financing research.
Sint Antonius Hospital, Nieuwegein

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Compare functional results of the three postoperative care regimens assessed with the Olerud-Molander ankle score 12 weeks after surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Indications for surgical treatment of ankle fractures are well defined, controversy exists with regard to the optimal postoperative treatment. Multiple postoperative care regimes exist and have been described as successful. However, an adequately powered prospective study comparing postoperative treatments and wound related problems is still lacking.

Objective:

The main objective of this multicenter prospective study is to compare functional outcome measured by the Olerud Molander Score at 12 weeks after operative fixation of an ankle fracture with three different postoperative care regimes. To be known: A) unprotected non-weight-bearing mobilisation with active exercises, B) protected weight-bearing mobilisation with a cast or C) unrestricted weight-bearing mobilisation with active exercises.

Study design:

This study is a prospective multicenter clinical study, which will be accomplished in three level 1 trauma centers (Academic Medical Center Utrecht, St. Elisabeth Hospital Tilburg, Medisch Centrum Haaglanden) and three large level 2 trauma centers (Antonius Hospital Nieuwegein, Diakonessenhuis Utrecht, Twee Steden Hospital Tilburg). Patients will be recruited at the emergency department and registered to the study. The indication for trial participation will be validated by an expert panel, who will classify the fracture based on the initial X-rays. After assessment and licensing by this panel, informed consent will be obtained. After open reduction and internal fixation patients will be randomised by a computerized blocked randomization and stratified by the participating hospitals. Patients who are allowed weight-bearing therapy will get a pressure-chip installed to their shoe or cast to analyse the weight distribution of the operatively fixed ankle during the first 6 weeks of rehabilitation. Reviews of the patients will be accomplished by the treating surgeon or investigator after 2, 6, 12 weeks, 6 and 12 months. Each visit includes physical examination, standardized clinical evaluation, registration of possible complications and completing the Olerud Molander and SF-36 questionnaires.

Study population:

Patients from 18 to 65 years will be included with fractures classified as Lauge Hansen supination-eversion 2-4 injury with concomitant articular discongruity of more than 2 mm.

Intervention:

After operative fixation of the ankle fractures, patients will be treated by one of the three treatment protocols, depending on randomisation: A) unrestricted non-weight-bearing mobilisation with active exercises, B) protected weight-bearing mobilisation with a cast or C) unrestricted weight-bearing mobilisation with active exercises.

Main study parameters/endpoints:

The Olerud Molander ankle score is the main study parameter/endpoint (12 weeks after surgery). Grouping of secondary endpoints results in three outcome groups: 1) Patient satisfaction (Olerud Molander Score, VAS for satisfaction, period of resumption to work, period of resumption to sports and period to pain free movement); 2) Medical parameters and safety (range of motion, clinical consolidation, radiologic consolidation, hardware failure and infection); 3) Biology of fracture healing (period to full weight bearing, degree of muscle wasting).

Doel van het onderzoek

The hypothesis of this study is that direct weight-bearing after operative fixation of ankle fractures, will shorten the period of assumption to work and/or sports and improve the range of motion of the affected ankle.

Onderzoeksopzet

1. 2 weeks;

2. 6 weeks;

3. 12 weeks;

4. 6 months;

5. 12 months.

Onderzoeksproduct en/of interventie

1. Unprotected non-weight-bearing mobilisation with active exercises and crutches;

2. Protected weight-bearing with a conventional walking cast;

3. Unrestricted weight-bearing mobilisation with active exercises.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients from 18 - 65 year;

2. Fractures classified as Lauge Hansen supination-eversion type 2, 3 or 4;

3. Articular discongruity of >2 mm on radiograph (international indication for surgery).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pre-existent impaired mobility;

2. Pre-existent cognitive disability;

3. Expected insufficiently stable fracture fixation with standard surgical technique;

4. Necessity for a syndesmosis screw;

5. Tertius fragment which requires operative fixation;

6. Body Mass Index > 30;

7. Diabetes mellitus;

8. Polytrauma patients (ISS>16 or >2 AIS regions involved);

9. Gustilo 2 and 3 open fractures;

10. Inability to comply with non-weight bearing mobilisation (i.e. due to other injuries / co-morbidity);

11. Inability to comply with follow-up (for example due to an inability to read or complete forms).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	225
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43927
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3568
NTR-old	NTR3727
CCMO	NL40835.100.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43927

Resultaten

Samenvatting resultaten
N/A