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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22736

Source
Nationaal Trial Register

Brief title
WOW

Health condition

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

Sponsors and support

Primary sponsor: Sint Antonius Hospital, Nieuwegein
Source(s) of monetary or material Support: self-financing research.
Sint Antonius Hospital, Nieuwegein

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Compare functional results and patient satisfaction of the three postoperative care regimens assessed by the Olerud-Molander ankle score, 6 weeks and 1 year after surgery;

2. Compare the rate of wound related problems after the three postoperative care regimens;

3. Compare the rate of hardware failure after the three postoperative care regimens;

4. Compare range of motion (plantar-flexion and dorso-flexion) of the ankle after the three postoperative care regimens after 6 and 12 weeks and 1 year after surgery;

5. Compare the amount of weight baring (chip results), calf wasting (determined by the difference between the injured leg preoperatively and the same leg postoperatively with respect to the circumference of the leg) and muscle strength 12 weeks post-operatively;

6. Compare the duration to radiologic consolidation after the three postoperative care regimens 6 and 12 weeks and 1 year after surgery;

7. Compare patient satisfaction measured by the visual analogue scale (VAS) and SF-36 questionnaire 6 and 12 weeks and 6 and 12 months after surgery;

8. Compare period of resumption to work after the three postoperative care regimens;

9. Compare period of resumption to sports after the three postoperative care regimens.

Study description

Background summary

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).

Study objective

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.

Study design

1. 2 weeks;

2. 6 weeks;

3. 12 weeks;

4. 6 months;

5. 12 months.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	225
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43927
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A