The treatment of stable ankle fractures: Brace versus Cast immobilization

No registrations found.

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

Summary

ID

NL-OMON23875

Source
NTR

Brief title
GiBra

Health condition

ankle fractures, Weber B

Sponsors and support

Primary sponsor: - Medical Center Haaglanden
- Bronovo Hospital
Source(s) of monetary or material Support: Medical Center Haaglanden

Intervention

Outcome measures

Primary outcome

Primary outcome is the Olerud & Molander Score at 6 weeks.

Secondary outcome

- pain
- comfort of cast / brace
- Range of motion
- long term function (using the AAOS foot and ankle score)
- health related quality of life using the EQ5D
- fracture dislocation
- presence of osteoarthritis at 1 year

Study description

Background summary

Ankle fractures are commonly seen on emergency departments of hospitals. They represent about 10% of all fractures and the incidence is expected to increase in the following years. n the case of an ankle fracture, the fibula (lateral malleolus) and/or the tibia (medial and/or posterior malleolus) can be injured. Furthermore, there can be ligament injury (mainly the syndesmosis between tibia and fibula en the deltoid ligament are of important value). The degree of osseous and/or ligament injury determines if the fracture is stable or unstable. In general, stable fractures are treated non-operatively (conservatively) and unstable fractures are treated operatively. The current treatment of stable ankle fractures in the Netherlands and most other Western European countries consist of 6 weeks cast immobilization: a below-the-knee plaster cast for 1-2 weeks non-weight bearing, followed by a fiberglass short leg walking cast for the next 4-5 weeks, bearing weight within the limits of pain. Disadvantages of this treatment are that after cast immobilization some stiffness in the ankle joint may develop, atrophy of the calf muscle occurs and there might be an increased risk of developing osteoporosis. In some countries, including Switzerland, stable ankle fractures are often treated with a functional brace. Some previous studies indicate that this functional treatment prevents fracture dislocation as well as cast immobilization does, although it results in better clinical outcome and more comfort. A recent Cochrane Review (2009) described that there is limited evidence that the use of a removable type of immobilization and performing exercises during the immobilization period result in a better outcome. They also indicate that more clinical studies are necessary to support the current evidence. Future trials need to be adequately designed, outcome measures and endpoints need to be clear and they need to be adequately powered so that the results can be conclusive.

The aim of this study is to examine if a functional brace in the treatment of Unimalleolar Weber-B fracture results in a higher Olerud and Molander Score, less pain, better comfort, greater range of motion.

This stydt is a multicenter, prospective clinical trial in Medical Center Haaglanden (The Hague) and Bronovo Hospital (The Hague). All patients presenting at the emergency department with a stable ankle fracture will initially be treated with cast immobilization, the current treatment. Patients that meet the inclusion criteria will be informed about the study at the emergency department and they get an information letter. One week after visit to the

emergency department there will be a check by the trauma-surgeon of the fracture by an ankle X-ray. If the fracture shows to be stable, they will be included in the study and randomization takes place under patients who are willing to participate in the trial. Group 1 will receive the current treatment with cast immobilization for a period of 5 weeks (non-weight bearing for 2 weeks and 3 weeks bearing weight within the limits of pain). Patients will be reviewed at 1 week, 3 weeks, 6 weeks, 12 weeks, 26 weeks and 52 weeks. After which both groups will be analyzed using SPSS version 20 or higher.

Study objective

This is study is to examine if a functional brace in the treatment of Unimalleolar Weber-B fracture results in a higher Olerud and Molander Score, less pain, better comfort, greater range of motion.

Study design

1 week
3 weeks
6 weeks
12 weeks
26 weeks
1 year

Intervention

At 1 week post fracture the patient will return to the clinic. If he/she is willing to participate in the trial the randomization will take place. Group 1 consists of patients treated with cast immobilization for a period of 5 weeks. Group 2 consists of patients treated with a functional ankle brace for a period of 5 weeks. Week 1: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Patient comfort using a Visual Analogue Scale Dislocation of the fracture using radiographs Euroqol-5D questionnaire Week 3: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Patient comfort using a Visual Analogue Scale Dislocation of the fracture using radiographs Euroqol-5D questionnaire Week 6: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Patient comfort using a Visual Analogue Scale Range of Motion Dislocation of the fracture using radiographs Euroqol-5D questionnaire Week 12: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Range of Motion Euroqol-5D questionnaire Week 26: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Range of motion Euroqol-5D questionnaire AAOS-score Week 52: Olerud & Molander Ankle Score Pain level using a Visual Analogue Scale Range of motion Euroqol-5D questionnaire AAOS-score The presence of arthrosis using radiographs (Ankle Osteoarthritis Scale)

Contacts

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Eligibility criteria

Inclusion criteria

Patients with a stable ankle fracture (type Weber B and less than 2 mm dislocation), between the age of 18 and 75 years old

Exclusion criteria

- Multiple fractures
- Mental handicap
- Patients not living in the right region, i.e. follow up takes place in a different medical centre.
- Patients who do not speak Dutch fluently

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):	01-02-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-03-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39792
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4323
NTR-old	NTR4469
CCMO	NL41177.098.12
OMON	NL-OMON39792

Study results