The WOW! Study, Weight-bearing or Non-Weight bearing. A prospective randomised multicenter comparison of three different care regimens after operatively fixed ankle fractures.

Published: 19-11-2012
Last updated: 15-05-2024

Primary Objective: Compare functional results of the three postoperative care regimens assessed with the Olerud-Molander ankle score 12 weeks after surgery.Secondary Objective(s): 1) Compare functional results and patient satisfaction of the three...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON43927

Source
ToetsingOnline

Brief title
The WOW! Study

Condition

- Fractures

Synonym
operated ankle fractures, operatively fixed ankle fractures

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ankle fracture, post-operative treatment regimes, surgical treatment, weight bearing

Outcome measures

Primary outcome

Olerud-Molander ankle score, 12 weeks after surgery

Secondary outcome

- Olerud-Molander ankle score (6 weeks and 1 year after surgery)

- Number of wound related problems

- Number of hardware failures

- Range of motion of the ankle (6 and 12 weeks and 1 year after surgery)

- Weight bearing, calf wasting and muscle strength (6 and 12 weeks)

- Radiologic consolidation (6 and 12 weeks and 1 year after surgery)

- Patient satisfaction: VAS and SF-36 (6 and 12 weeks and 6 and 12 months)

- Period of resumption to work

- Period of resumption of sports

- Analysis of weight distribution of the operatively fixed ankle

Study description

Background summary

Fractures of the ankle occur frequently with an overall estimated incidence of approximately 100-150 fractures per 100.000 person-years. The most common

causes of ankle fractures are twisting injuries and falls, followed by sports injuries. The peak incidence is seen in young men and older women.

Surgical treatment, generally open reduction and internal fixation, is indicated when congruity of the ankle joint has been compromised [3]. Important goals of the postoperative care regimes are early functional recovery and quick resumption of work for the young and active patient population.

Postoperative care regimes vary widely. Results from plaster casts, removable casts, functional bracing, walking boots, unprotected non-weight-bearing exercises and unprotected weight-bearing are described. The two most commonly used postoperative care regimens after ankle fractures in the Netherlands are weight-bearing with a conventional cast and non-weight-bearing functional mobilisation with active exercises. The studies of both Finsen (1989) and van Laarhoven (1996) described a temporary benefit at 6 weeks post-operatively for those patients treated with a below-knee walking plaster in comparison to unprotected non-functional treatment (Appendix 1). At one year follow-up, no significant differences were found between these two types of treatment and an individual based decision was advised.

Early weight-bearing and the avoidance of complete immobilization have been shown to decrease the development of soft-tissue atrophy and to prevent the development of osteoporosis. In the unprotected treatment a comparison is made between non-functional and functional aftercare. In this latter group, daily exercises were advised. In the Cochrane review all ten studies demonstrated significant improved outcome for the functional treatment group, which facilitates the restoration of the range of motion of the injured joint, less pain and higher quality of life scores. This treatment is described as a safe and experimental treatment.

A functional brace has the theoretical advantage of both weight-bearing and the possibility to exercise. However, no clinical significant difference was found in four studies included in the Cochrane review. This could be partially due to the rather complicated use of these orthesis and thereby diminished patient compliance.

The Cochrane review ends with the following statement: *Priority should perhaps be first directed towards investigating the effectiveness and safety of interventions that are in common use, such as the effects of exercise and weight-bearing if started during the period of immobilisation.* In concordance to this statement, 3 authors published their results on immediate mobilisation and unprotected weight bearing in relatively stable ankle fractures. Simanski et al, Gul et al and Partenheimer et al showed that there were even no disadvantages and demonstrated high patient satisfaction scores. Treatment without cast would result in earlier full weight bearing toleration and thereby faster rehabilitation with full walking ability within 5 weeks.

Essential for safe early full weight bearing is selection of suitable patients. The Lauge Hansen classification for ankle fractures describes best the intrinsic stability of the ankle joint, as it demonstrates the trauma mechanism and thereby incorporates the ligament injuries. The Weber classification only describes the lateral malleolus. The AO classification only describes fracture patterns and does not implement ligament injuries. Thus the classification best suitable for selecting the correct patient and fracture type in the present study is the Lauge Hansen classification. Fractures which are relatively stable and therefore suitable for immediate post-operative full weight-bearing are Lauge-Hansen supination-eversion type 2, 3 and 4. Indications for surgical treatment of ankle fractures are clear, however controversy exists with regard to the optimal postoperative care regime. This trial is designed and powered to strengthen current evidence about the effectiveness of postoperative care regimes after ankle fractures and analyse a new post-operative care regime, as was suggested in the Cochrane review.

A novelty in analyzing patient rehabilitation is the SensiStep. This is a pressure chip, which can be implanted in a cast or sole of a shoe. This device is developed by the medical innovation organization Pontes Medical and marketed by Evalan. In patients in the weight bearing groups, the insole sensor will be applied in a standardized shoe (sandal) for examination of the loading pattern of the operatively fixed ankle during revalidation. The chipresults can be used in the future to correct, if necessary, the loading pattern of patients during rehabilitation after operative fixation of ankle fractures.

The primary objective of this prospective randomised multicenter study is to compare functional outcome after three different postoperative care regimens:

A) unprotected non-weight-bearing mobilisation with active exercises and crutches
B) protected weight-bearing with a conventional walking cast
C) unprotected weight-bearing mobilisation with active exercises

The primary outcome will be measured by the Olerud Molander score. This scoring system is a well known measurement instrument in scientific research, which can separate even minor differences in disability in daily activities. A difference in 5-10 points is defined as a significant result. The period of resumption to work and sport activities will also be analysed during this research and correlated to the SF-36 questionnaire. By this multicenter trial, and its corresponding sample size, it is thereby expected that a difference of 7 points in the Olerud Molander will represent a complete analysis of the recovery process of the patients, including sport and work activities.

Study objective

Primary Objective:
Compare functional results of the three postoperative care regimens assessed

with the Olerud-Molander ankle score 12 weeks after surgery.

Secondary Objective(s):

1) Compare functional results and patient satisfaction of the three postoperative care regimens assessed by the Olerud-Molander ankle score, 6 weeks and 6, 12 months 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 6, 12 months 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 design

Design: Prospective randomised multicenter clinical study

Duration: 4 years

Setting:
Two level 1 trauma center:
- Academic Medical Center Utrecht
- St. Elisabeth Hospital, Tilburg

Four level 2 trauma centers:

- Antonius Hospital, Nieuwegein
- Diakonessenhuis, Utrecht
- Twee Steden Hospital, Tilburg
- Medisch Centrum Haaglanden, 's-Gravenhage

Intervention

* A) Unprotected non-weight-bearing group:
A compression bandage is placed directly after surgery. The bandage can be removed 24 hours postoperatively and patients will be allowed to move the ankle joint. Active exercises, dorso-flexion, plantar-flexion and rotation of the foot, are recommend three times a day during approximately 5 minutes. Weight bearing is not allowed for 6 weeks. After 6 and 12 weeks the pressure load will be measured by scale.

* B) Protected weight-bearing (conventional cast) group:
A below knee non-weight bearing plaster of Paris is placed directly after surgery. After 2 weeks the cast will be removed, a new below knee walking cast is applied and full weight bearing is allowed when it can be performed without pain. A microchip (SensiStep) will be installed in their cast to analyse the weight distribution of the operatively fixed ankle during revalidation. The cast will be removed 6 weeks post-operatively. *After 2,6 and 12 weeks the pressure load will be measured by scale.*

* C) Unprotected weight-bearing group:
Comparable to the non-weight bearing group, a compression bandage will be placed directly after surgery. The bandage can be removed after 24 hours, which will allow movement to the ankle joint. Active exercises, Active exercises, dorso-flexion, plantar-flexion and rotation of the foot, are recommend three times a day during approximately 5 minutes. After the compression bandage is removed, full weight bearing of the ankle is allowed when it can be performed without pain. Patient will be to mobilise with a customised standardised shoe, with a microchip installed in their sole of their shoe to analyse the weight distribution of the operatively fixed ankle during revalidation. Results will be reviewed after 6 weeks. From that moment on, it is not necessary anymore for patients to mobilise with the standardised shoe. After 2,6 and 12 weeks the pressure load will be measured by scale.

Due to the development of the Sensistep, the pressure load will be measured randomly by the Sensistep in group C.

In general, all patients will attend the care of a physiotherapist during the intervention period.

Study burden and risks

The indication for surgery is unrelated to the study. Participation is completely voluntary and can be aborted at any time of the study without consequences. This study includes in total 5 visits to the outpatient department, after 2, 6, 12 weeks, 6 months and 1 year. These visits are part of standard post-operative care regimes. Each visit includes physical examination, standardized clinical evaluation, registration of possible complications and in addition completing an Olerud-Molander and SF-36 questionnaire. Participation in this study does not provide supplementary risks besides the standard complications of surgery, such as wound infections, damage due to pressure of the cast, deep venous thrombosis or hardware failure. Insurance is vacant for every participant in case of unexpected damage due to this study.

Contacts

Public
Diakonessenhuis Utrecht

Bosboomstraat 1
Utrecht 3582 KE
NL
Scientific
Diakonessenhuis Utrecht

Bosboomstraat 1
Utrecht 3582 KE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients from 18-65 years
fractures classified as Lauge Hansen supination-eversion type 2,3 or 4
articular discongruity of > 2 mm on radiograph (international indication for surgery)

Exclusion criteria

Pre-existent impaired mobility
Pre-existent cognitive disability
Expected insufficiently stable fracture fixation with standard surgical technique
Use of syndesmosis screw
Tertius fragment which requires operative fixation
Body Mass Index > 30
Diabetes mellitus
Polytrauma patients (ISS>16 or >2 AIS regions involved)
Gustilo 2 and 3 open fractures
Inability to comply with non-weight bearing mobilisation (i.e. due to other injuries / co-morbidity)
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
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-02-2013
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO Date:	19-11-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-07-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22736
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL40835.100.12
OMON	NL-OMON22736