Research on the difference in effectiveness between the treatment with plaster versus pressure bandage after hallux valgus correction

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The aim of the study is to determine the difference in effectiveness in the treatment of a hallux valgus correction with 2 weeks cast versus pressure bandage treatment with 2 weeks, both followed by 4 weeks with a spica and Post-op shoe.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON39597

Source
ToetsingOnline

Brief title
nvt

Condition

- Joint disorders

Synonym
deformity of the big toe, malalignement big toe

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis

Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: after treatment, follow-up treatment, hallux valgus

Outcome measures

Primary outcome

The primary endpoint is the VAS satisfaction score

Secondary outcome

Secondary endpoints are: VAS pain score, and recurrence hallux valgus, Position sesamoidea, wound (redness, infection, blisters), MTP1 joint function, AOFAS hallux score, Complications

Study description

Background summary

Hallux valgus is a deformity of the first ray. The metatarsal 1 is directed medially, while dig 1 is directed laterally. This creates a bunion at the level MTP joint on the medial side of the foot. This may lead to a bursitis. The deformity and bursitis can cause pain, especially when wearing shoes. In addition, the deformity can cause aesthetic complaints.
The operation is aimed at pain reduction and a better fit in footwear.
There is little / no literature available on the standard treatment after surgical correction of the hallux valgus deformity. This varies from shoe cast to a spica with a post-op shoe. With also variations in duration of treatment, such as 2weeks no weightbearing versus 4 weeks no weightbearing. It also appears that the risk of recurrence and complications is independent of the chosen treatment.
The correction is a fixed osteosynthesis, thereby it is to be expected that immobilization with a cast is not necessary. In many other hospitals pressure bandage is already the standard treatment.
In the manuals foot and ankle surgery a bandage with use of a wedge shoe is recommended as treatment with no weightbearing the first 2-4 weeks. Cast Shoe treatment only if the osteotomy or fixation should be protected.
There are no recent publications on recurrence rates, wound healing disorders and patient satisfaction associated with comparative studies on pressure

bandage versus cast.
However, there is a study of the after treatment of a Lapidus procedure, herein is found that only a bandage with a wegde schoe is sufficient

Study objective

The aim of the study is to determine the difference in effectiveness in the treatment of a hallux valgus correction with 2 weeks cast versus pressure bandage treatment with 2 weeks, both followed by 4 weeks with a spica and Post-op shoe.

Study design

It is a Randomised Controlled Trial.
118 patients : 59 patients cast (control group) given after surgery and 59 patients pressure bandage (intervention) after surgery

The 14th day postoperatively, the patients in both groups return to the cast clinic to remove the pressure bandage / cast and there will be a wound inspection by the doctor, also the stitches are removed. After this, every patient has a spica applied for 4 weeks. Postoperatively, the patient is asked at each control pain and satisfaction scores, this can be done using validated assessment tools. 12 weeks postoperatively and 1 year postoperatively, the function of the MTP1 joint is re-examined and at the last audit 1 year postoperatively the AOFAS Hallux score will be recalculated.
Radiographs are preoperatively, 6 and 12 weeks postoperatively and 1 year postoperatively made**.

Intervention

Group 1 receives a cast after the operation (standard)
Group 2 will receive a pressure bandage after surgery (intervention)

Study burden and risks

Risks, patients are not at extra risk when participating in the study. The risks that could arise are related to the surgery. These risks one runs even if one does not join the study

Burden: The extra burden on participants is completing questionnaires and keeping a pain and satisfaction diary the first 14 days postoperatively.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

primary, elective hallux valgus correction in the form of: Akin, scarf osteotomy or Chevron osteotomy
>18 year
signed informed consent
understand / read Dutch language regarding completion questionnaire

Exclusion criteria

no signed informed consent
patients undergoing hallux valgus correction and also a hammer toe correction with k-wires are used

inability to use two crutches to mobilize

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2013
Enrollment:	118
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	16-10-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL39794.094.12