Chevron osteotomy: immobilisation by cast or walking boot?

No registrations found.

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

Summary

ID

NL-OMON24582

Source
NTR

Health condition

- Hallux valgus
- chevron osteotomy
- immobilisation
- plantar pressure

Sponsors and support

Primary sponsor: Dept. of Orthopaedics
Martini Hospital Groningen
P.O. Box 30033
9700 RM Groningen
Source(s) of monetary or material Support: Dept. of Orthopaedics
Martini Hospital Groningen
P.O. Box 30033
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Intervention

Outcome measures

Primary outcome

Proportion patients with a loss of more than 5 degrees of the correction of the hallux valgus angle (HVA), one year following surgery

Secondary outcome

- Difference in (the course of regression of the) HAV and intermetatarsal 1 and 2 angle (IMA)

- plantar pressure: peak pressure of eight regions in the forefoot

- Physical functioning

- Health-related quality of life

Study description

Background summary

Deformity of the big toe is a common orthopedic problem, and 33% of the general Dutch population has a hallux valgus. This deformity of the big toe can ultimately lead to pain and gait deviations. A symptomatic hallux valgus is often treated surgically, to correct the anatomic deformity. The Chevron osteotomy is a much used surgical technique for this. Postoperative immobilisation can be done by means of a plaster cast or a removable walking boot. An advantage of the walking boot is that it is more comfortable compared to a plaster cast. However, it is unknown whether immobilisation by means of the walking boot results in a remained correction of the hallux valgus. The hallus valgus correction might be better preserved by means of a plaster cast, becaus the reefed capsule gets a better change for scarring in the by surgery obtained position. To date, there is a lack of studies in which the effectiveness of the two types of postoperative immobilisation following Chevron osteotomy - a plaster cast or a removable walking boot - has been compared.

Primary aim of the study is to compare the preservation of the correction of hallux valgus angle by means of a Chevron osteotomy with postoperative immobilisation by means of a plaster cast or a removable walking boot, one year following surgery. Secondary aims are to compare the effectiveness of the immobilisation by means of a plaster cast or a walking boot for the recovery of plantar pressure during walking, and recovery of physical functioning and health-related quality of life.

A prospective randomised controlled trial will be conducted. Two types of postoperative immobilisation following Chevron osteotomy wil be compared. The control group will receive postoperative immobilisation by means of a removable walking boot. The study group will

receive postoperative immobilisation by means of a (non-removable) plaster cast. Measurements will take place preoperatively, and 6 weeeks, 3, 6 and 12 months postoperatively.

Study objective

Immobilisation by means of a plaster cast will result in a better correction and retaining of the hallux valgus correction at one year following chevron osteotomy.
Additionally, it is hypothesised that immobilisation by means of a plaster cast will also result in a better recovery of plantar pressure during walking, and a better recovery of physical functioning and health-related quality of life.

Study design

- Preoperatively

- 6 weeks postoperatively

- 3 months postoperatively

- 6 months postoperatively

- 1 year postoperatively

Intervention

Treatment of the study group (Chevron osteotomy with postoperative immobilisation by means of a plaster cast): Postoperative immobilisation following Chevron osteotomy will be performed by means of a (non-removable) plaster cast, for a period of six weeks. Only partial weightbearing is allowed (only the heel). This plaster cast will be created by a master caster.

Treatment of the control group (Chevron osteotomy with postoperative immobilisation by means of a removable walking boot): Postoperative immobilisation following chevron osteotomy will be performed by means of a removable walking boot, for a period of six weeks. Complete weightbearing is allowed. This walking boot will be created by an orthopedic shoemaker.

Contacts

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Eligibility criteria

Inclusion criteria

- at least 18 years old

- mild symptomatic hallux valgus: intermetatarsal 1 and 2 angle (IMA) of < 16 degrees, and a hallux valgus angle (HVA) of < 30 degrees

Exclusion criteria

- Diabetes mellitus

- Rheumatoid arthritis

- Prednison use

Study design

Design

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

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-11-2013
Application type:	First submission

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
NTR-new	NL4106
NTR-old	NTR4251
Other	METC : RTPO 910
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A