

Chevron osteotomy: immobilisation by cast or walking boot?

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24582

Bron

NTR

Aandoening

- Hallux valgus
- chevron osteotomy
- immobilisation
- plantar pressure

Ondersteuning

Primaire sponsor: Dept. of Orthopaedics

Martini Hospital Groningen

P.O. Box 30033

9700 RM Groningen

Overige ondersteuning: Dept. of Orthopaedics

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 hallux valgus correction might be better preserved by means of a plaster cast, because 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 will 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 weeks, 3, 6 and 12 months postoperatively.

Doel van het onderzoek

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.

Onderzoeksopzet

- Preoperatively
- 6 weeks postoperatively
- 3 months postoperatively
- 6 months postoperatively
- 1 year postoperatively

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Diabetes mellitus
- Rheumatoid arthritis
- Prednison use

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	20-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4106
NTR-old	NTR4251
Ander register	METC : RTPO 910
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A