

Lange termijn resultaten van de Scarf en Chevron correctie osteotomie voor de correctie van Hallux Valgus. Een prospectief, gerandomiseerd onderzoek met meer dan 12 jaar opvolging.

No registrations found.

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

Summary

ID

NL-OMON21461

Source

NTR

Brief title

Hallux valgus, Scarf, Chevron, RCT, lng term follow up

Health condition

Hallux valgus, scarf , chevron osteotomy, RCT, Deenik et al. 2007

Sponsors and support

Primary sponsor: NA

Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

The primary endpoint will be the recurrence rate of hallux valgus and reoperation rate of the same toe for hallux valgus.

Secondary outcome

Comparing the initial results from the study with the long-term results between the scarf and chevron osteotomy.

The secondary endpoints will be the results from the SF-36, Kitaoka /AOFAS rating system, MOXFQ and radiographic measurements IMA and HVA. The IMA is measured as the angle between the line of the first metatarsal and the line bisecting the diaphyseal portions of the second metatarsal. The HVA is measured as the angle between the line from the center of the metatarsal base to the center of the first metatarsal head and the line connecting the midpoints of the proximal and distal articular surfaces of the proximal phalanx.

Study description

Background summary

In 2007 Deenik et al published a randomized controlled trial comparing the scarf versus the chevron osteotomy in the treatment of hallux valgus. There were no significant differences after 27 months of follow up. Due to more technical demands of the scarf osteotomy the authors concluded that the chevron osteotomy was the first choice in the treatment of hallux valgus.

The study of Deenik was conducted in the Maasland Hospital, today known as Atrium-Orbis Medical Centre. Since then no other studies have been performed comparing these widely used operative techniques. The aim of this follow-up study is to compare the status of the hallux valgus of these same patients after more than 12 years of follow-up. We will use the same questionnaires and radiographic measurements as the original study as well as the Manchester-Oxford Foot Questionnaire (12-item MOXFQ). The aim of this study is to determine the long-term effects of both operative techniques.

Study objective

We hypothesize that there is no difference in survival, clinical and radiological follow-up after >12 years of follow-up between the scarf and chevron osteotomy.

Study design

Pre-, 3, 12, 27 months and >12 years post operative.

Intervention

Hallux valgus correction: Chevron vs. Scarf

Contacts

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Eligibility criteria

Inclusion criteria

- o Participated in previous RCT by Deenik et al (2007).

Exclusion criteria

- o Patients who developed systemic joint disease, e.g. rheumatoid arthritis.
- o Psychiatric patients.
- o Patients who don't want to contribute to this follow-up.

Study design

Design

Study type: Interventional
Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2015
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	07-05-2015
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	NL5081
NTR-old	NTR5213

Register

Other

ID

METC Atrium-Orbis-Zuyd : 15-T-55

Study results

Summary results

Deenik et al (2007). Scarf versus chevron osteotomy in hallux valgus: a randomized controlled trial in 96 patients. Foot Ankle Int.

Jeuken, Ralph M., et al. "Long-term Follow-up of a Randomized Controlled Trial Comparing Scarf to Chevron Osteotomy in Hallux Valgus Correction." Foot & Ankle International (2016): 1071100716639574.