The effect of postoperative physiotherapy, after Chevron osteotomy, on foot function. A randomized controlled trial.

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Evaluation of the effect of postoperative physiotherapy, after Chevron osteotomy, on foot function.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON35856

Source
ToetsingOnline

Brief title
Physiotherapy after hallux valgus correction

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Deviation of big toe. Big toe deformity.

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: vanuit vakgroep orthopedie

Intervention

Keyword: Chevron osteotomy, Foot function, Hallux valgus, Physiotherapy

Outcome measures

Primary outcome

AOFAS Hallux score

Secondary outcome

Function of first MTP-joint:

Foot Function Index

VAS pain/satisfaction/ cosmesis

Study description

Background summary

Minor qualitative studies have focussed on postoperative treatment after a hallux valgus correction. Conflicting results have been reported regarding postoperative foot function, after correction of hallux valgus.
Objective of the study:

Evaluation of the effect of postoperative physiotherapy, after Chevron osteotomy, on foot function.

Study objective

Evaluation of the effect of postoperative physiotherapy, after Chevron osteotomy, on foot function.

Study design

Randomized controlled trial in a single centre, with one year follow-up. Two groups: 1. with postoperative physiotherapy 2. without postoperative physiotherapy. Approximately 30 patients per group.

Intervention

postoperative physiotherapy, consistent with a specific treatment protocol.

Study burden and risks

no risks, as result of inclusion in this study. Patients randomized to the physiotherapy group will undergo several sessions of physiotherapy. Both groups will be asked to fill out several questionnaires, during their visits to the outpatient clinic. This will lead to extra time. All other aspects pre and postoperatively are normal activities and efforts, as result of normal patient care, apart from the study.

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

-Patients with an indication for Chevron osteotomy:

Intractable pain isolated to the first or second MTP joint region, associated with a hallux valgus deformity, refractory to conservative treatment (shoe modifications, NSAIDs, modification of activities etc)., with following rontgenographic details:
*Intermetatarsal Angle<=20 degrees ;-Age 18-65.
-Physiologic preoperative gait pattern

Exclusion criteria

Specific comorbidity:;Inflammatory arthritis, degenerative arthritis of the first MTP joint, previous foot surgery, juvenile hallux valgus, rheumatoid arthritis, diabetes mellitus, peripheral vascular disease, neuropathy, neuromuscular disease, active infection, incompetent person

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
Other	2978
CCMO	NL37199.075.11