Hallux valgus: Minimally invasive Chevron and Akin procedure versus open Chevron osteotomy

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To objectify a significant difference in the degree and preservation of the correction between minimally invasive and open treatment in patients with hallux valgus deformity. Also a significant difference in return to normal shoe wear, pain and...

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

Summary

ID

NL-OMON50310

Source
ToetsingOnline

Brief title
MICA

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
crooked big toe, hallux valgus

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hallux valgus, minimally invasive chevron and akin, open chevron osteotomy, percutaneous technique

Outcome measures

Primary outcome

The primary outcome is the degree and preservation of the correction of the

hallux valgus.

Secondary outcome

Secondary endpoints are pain, return to normal shoes and stiffness in MTP-1

joint.

Study description

Background summary

Hallux valgus is a common condition with progressive anomaly of the first ray. More than 150 operations have been described for the treatment of hallux valgus. Distal metatarsal (MT) open chevron osteotomy (combined with Akin) is a good option in mild to moderate hallux valgus. In recent years there has been a growing interest in the use of minimally invasive techniques. The minimally invasive Chevron and Akin (MICA) technique is also used for mild to moderate hallux valgus. Mostly case series studies have been done comparing these two techniques. The need for a randomized controlled trial comparing MICA and open Chevron osteotomy is increasing.

Study objective

To objectify a significant difference in the degree and preservation of the correction between minimally invasive and open treatment in patients with hallux valgus deformity. Also a significant difference in return to normal shoe wear, pain and stiffness in MTP-1 joint between the two techniques is expected.

Study design

The design of this study is a surgeon based randomized study where patients will be observed for at least one year. Patients will be randomized to either

the MICA or open Chevron procedure. MICA procedure will be performed by dr. S.B. Keizer and open Chevron procedure by dr. A.R. Deenik. Patients included will be subjected to four radiographic moments with 2 photos each moment (AP en lat): one before and three after the operation (six weeks, three months and one year). All radiographs will be taken in a weight bearing anterior-posterior and lateral position. Subsequently, they are observed for a year with multiple outpatient visits and completion of questionnaires (FAOS, MOXFQ, FFI, EQ5D, SF-12, VAS).

Study burden and risks

Patients will visit the outpatient clinic four times (with questionnaires to be filled in) and will get four radiographs of the foot (that is two extra radiographs above the normal amount). Each extremity radiograph (e.g. foot) exposes the patient to <0.01mSv. This means that included patients will receive <0.04mSv extra per included foot. This amount is negligible compared to the yearly background radiation at sea level (2-3 mSv). According to the guidelines of the ICRP occasional diagnostic radiography of the extremity is highly unlikely to cause malignancy.

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

1.Patient with hallux valgus deformity: mild to moderate severity (HVA up to 40° and IMA up to 20°)
2.Male or non-pregnant female aged 18-90

Exclusion criteria

1. Earlier foot surgery
2. Earlier fracture any bone of the foot, with exception for phalanx of digitus II-V fracture
3. Cerebral palsy
4. Rheumatoid arthritis
5. Not motivated for inclusion
6. Pregnant patients
7. Diabetes

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	13-04-2016
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	02-02-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL54013.098.15