Wel of geen K-draad plaatsen bij een hamerteencorrectie?

No registrations found.

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

Summary

ID

NL-OMON27420

Source
Nationaal Trial Register

Brief title
K-Toe

Health condition

fixed hamertoe
surgery
k-wire
correction

Sponsors and support

Primary sponsor: Maxima MC
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

AOFAS lesser toe metatarsophalangeal scale one year after surgery.

Secondary outcome

AOFAS lesser toe metatarsophalangeal scale score after 6 weeks.

Satisfaction (VAS)

Complications between the two techniques:

- infection (combination of new or increasing pain, erythema, local warmth and swelling and/or purulent discharge)

- deep venous thrombosis of the ipsilateral leg (diagnosed by ultrasound)

- vascular problems (necrosis of the skin of the toe 2,4,6 weeks or 1 year after the operation)

Toe position one year after surgery (Part of the AOFAS lesser toe metatarsophalangeal scale)

Requirement for revision surgery e.g as indicated by infection or malalagniment.

Study description

Study objective

It is hypothesized that both surgical techniques do not make more than 10 points difference in the American Orthopaedic Foot and Ankle Society (AOFAS) lesser toe metatarsophalangeal scale, one year after surgery.

Study design

baseline (preoperative)

postoperative:

6 weeks, and 1 year

Intervention

Dorsal incision over the deformed PIP joint, cleavage of the extensor tendon, opening and release of the joint capsule, resection of the distal condyles of the proximal phalanx,

resection of the sharp edges of the bone, wound irrigation with NaCl, verification of position, randomization for group A or B.

A. Placement of the K-wire inside out, outside in through the distal, mid and proximal phalanx. Wound closure with Donati sutures of monocryl.

B. Wound closure with Donati sutures of monocryl.

Continuous pressure bandage for 7 days, and weight bearing as tolerated in a special shoe for 4 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

Patients older than 18 years, diagnosed with hammer toe 2nd, 3rd, or 4th toe.

Exclusion criteria

Other current foot problem at the same foot.

Other foot surgery should be performed in the same session.

Patients with invalidating rheumatoid arthritis.

Patients with insulin depending diabetes mellitus.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	46
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-05-2014
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	NL4461
NTR-old	NTR4584
Other	METC Maxima MC : 1401

Study results