Fixed hammer toe correction, surgery with or without K-wire stabilisation?

Published: 01-05-2014
Last updated: 24-04-2024

Comparing two method 's of surgical hammer toe correction. Make clear the value of the K-wire.We use questionnaires about function and pain, patient satisfaction, complication registration, position controle of the toe and x-rays to achieve our…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50477

Source
ToetsingOnline

Brief title
K-toe

Condition

- Bone and joint therapeutic procedures

Synonym
digitus malleus, Hammer toe

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Reiskosten vergoeding en uitrijdkaarten zullen vanuit de stichting AA onderzoek en wetenschap vanuit de maatschap orthopedie worden betaald.

Intervention

Keyword: correction, Hammer toe, K-wire, surgery

Outcome measures

Primary outcome

AOFAS (American Orthopaedic Foot and Ankle Society) lesser toe

metatarsophalangeal scale

Secondary outcome

Patient satisfaction (VAS)

Complications (infection, deep venous thrombosis).

Revision surgery.

Postoperative X-ray.

Toe position after one year.

Study description

Background summary

For the surgical correction of hammertoes there are several surgical options.
In our clinic, we mostly use the pip joint resection with four weeks of K-wire fixation. After four weeks the K-wire is removed at the outpatient clinic.
After the removal patients can wear their normal footwear.
There are also variants where no surgical fixation with K-wire is used.
K-wire fixation has several disadvantages:
- Porte d'entrée for infection
- Discomfort to the patient
- Additional costs
- Longer duration of surgery
- Needlestick injury hazard

No fixation of the toe will possibly lead to a position of the toe which is not as good as the position after K-wire fixation.

So, with this study we want to compare both methods and their advantages and

disadvantages. And make clear the value of the K-wire.

Study objective

Comparing two method 's of surgical hammer toe correction. Make clear the value of the K-wire.
We use questionnaires about function and pain, patient satisfaction, complication registration, position controle of the toe and x-rays to achieve our goal.

Study design

In a prospective randomized controlled trial, we will evaluate pre- en postoperative (6 weeks and 1 year) function, pain and satisfaction in 23 patients in group A with a fixed hammertoe deformity after surgery with K-wire fixation and 23 patients in group B without K-wire fixation. Both surgical techniques are standardized.
Randomization takes place during the surgery at the moment of placing the K-wire or closing the wound. Using this, we are confident that randomizationhas no effect on the surgical procedure.
At 2, 4 and 6 weeks and one year after operation we see the patients in the outpatient clinic:

* week 2 inspection of the wound and record complications,
* week 4 removing K-wire in group A and record complications,
* week 6 X-ray, fill in the AOFAS lesser toe metatarsophalangeal scale and ask for patient satisfaction,
* one year for examination of the toe position, fill in the AOFAS lesser toe metatarsophalangeal scale and ask for patient satisfaction.

Surgical technique:
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, randomization for group A or B.

A. Placement of the K-wire inside out, outside in through the distal, mid and proximal phalanx.
Position control, if correct close the skin with Donati sutures of monocryl.
B. Wound closure with Donati sutures of monocryl.

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

Intervention

Surgical technique:
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, randomization for group A or B.

A. Placement of the K-wire inside out, outside in through the distal, mid and proximal phalanx.
Position control, if properly close the skin with Donati sutures of monocryl.
B. Wound closure with Donati sutures of monocryl.

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

Study burden and risks

There are no other risks or loads, except the three questionnaires and additional outpatient visit 1 year post-operatively, compared with the patients who received "normal" treatment.

Contacts

Public
Maxima Medisch Centrum

Dominee Theodor Fliednerstraat 1
Eindhoven 5631 BM
NL
Scientific
Maxima Medisch Centrum

Dominee Theodor Fliednerstraat 1
Eindhoven 5631 BM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age > 18
Hammer toe 2,3 or 4th toe
One surgical procedure
No other actual foot problems

Exclusion criteria

Age<18
Other footproblems
Other footsurgery during same procedure
Reumatoid arthritis
Insulin dependent diabetes Mellitus

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2014

Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-07-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-12-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-03-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL47261.015.13