Is there a difference in result between PIP resection arthroplasty and PIP artrodesis in the treatment of rigid claw toes?

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To indentify the surgical intervention with the best result in case of a rigid claw toe.

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

Summary

ID

NL-OMON30559

Source
ToetsingOnline

Brief title
Surgical treatment of rigid claw toes

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
claw toe, MTP extension and PIP flexion deformity

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: vakgroepen orthopedie;onderzoeksfonds

Intervention

Keyword: Claw toes, Rigid, Surgery, Treatment

Outcome measures

Primary outcome

Kitaoka foot/ ankle score (=AOFAS score)

Secondary outcome

VAS pain score

X- ray foot

Physical examination

Satisfaction scale

Nijmegen classification

Cosmetic scale

Mobility scale

Study description

Background summary

The incidence of symptomatic lesser toe deformities, like claw toes, in the literature ranges from 2 to 20%. Interventions of lesser toe deformities are among the most performed procedures in general orthopaedic pratice.There is a variation in surgical methods to correct claw toes.
It is striking there is no international consensus in the treatment of a claw toe deformity. A prospective study will need to correct indistinctnesses and to result in standardized guidelines in the treatment of these deformities.

Study objective

To indentify the surgical intervention with the best result in case of a rigid claw toe.

Study design

A prospective randomised multi centre study will be conducted. The patient needs to sign the informed consent before randomisation. After randomising every patient will be designated to one of the two methods of surgery. The two methods will be: a PIP- resection arthroplasty or a PIP- arthrodesis. In both study groups the MTP joint will be corrected by means of "soft tissue release". All patients, who meet the inclusion criteria as described below, with (a) symptomatic rigid claw toe(s) and an indication for surgery, will be randomised for one of the two surgical methods. After information and signing the "informed consent" form the patients will be included in the study.

Intervention

Surgery; one of the two methods:

1. PIP- resection arthroplasty
2. PIP- arthrodesis

If necessary: correction of hallux valgus.

Study burden and risks

Every outpatient visit of the included patient will have a duration of about 60 minutes. Then a X- ray of the foot will be performed, the patient will be interviewed, physical examination will be performed and the patient will have to fill out specific questionnaires. Next to these visits there will not be any other burden for the patient, related to this study.
Except for the known risks related to surgery, there are no extra risks related to this 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

One or multiple claw toe deformities
A rigid deformity
Age 20-85 yrs

Exclusion criteria

*Surgical intervention of toe(s), performed prior to study procedure
*Simultaneous intervention of the foot, except for toe surgery
*Comorbidity: arterial insufficiency, complex regional pain syndrom (CRPS), diabetes mellitus, neuropathy
*Underlying diseases which need to be treated before study procedure (i.e. cavus foot, ulcera)
*Generalized joint diseases (i.e. reumathoid arthritis)
*Impaired mobility as result of other pathology (hemiplegia, situation after aputation)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	01-10-2007
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO

Date:	18-04-2013
Application type:	Amendment
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
CCMO	NL15432.075.06