

The difference in result between the Hoffman's procedure and release of the MTP joints in the correction of deformities of the MTP joints in the reumatoid arthritic foot.

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To identify if soft tissue correction of the MTP joints compared to resection of the metatarsal heads (Hoffman's procedure), in patients suffering from reumatoid arthritis, has better outcome; in both study groups PIP resection arthroplasty and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON30500

Source

ToetsingOnline

Brief title

Correction of MTP deformities in the reumatoid arthritic foot.

Condition

- Tendon, ligament and cartilage disorders
- Bone and joint therapeutic procedures

Synonym

forefoot deformities, metatarsophalangeal joint deformities

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: vakgroepen;onderzoeksfonds

Intervention

Keyword: Hoffman's procedure, MTP deformities, MTP release, Reumatoid arthritis

Outcome measures

Primary outcome

Kitaoka foot/ ankle score (=AOFAS score)

Secondary outcome

VAS pain score

X- ray of the foot

Physical examination

Satisfaction scale

Nijmegen classification

Cosmetic scale

Mobility scale

Study description

Background summary

Almost 90% of the patients, suffering from reumatoid arthritis, has symptoms of foot deformities. Most of the times there is a combination of hallux valgus with progressive dorsal subluxation of the lesser MTP joints.

In case of MTP deformities in patients with reumatoid arthritis there is not always uniformity in which surgical procedure to apply. One may choose between resection of the metatarsal heads (Hoffman procedure) and soft tissue correction.

In the literature there are no prospective randomized studies about lesser toe surgery in patients suffering from reumatoid arthritis. A prospective study

needs to correct indistinctnesses and needs to result in an empirical basis for the intervention of first choice in specific arthritic deformities.

Study objective

To identify if soft tissue correction of the MTP joints compared to resection of the metatarsal heads (Hoffman's procedure), in patients suffering from rheumatoid arthritis, has better outcome; in both study groups PIP resection arthroplasty and MTP 1 arthrodesis will be performed during the same operation.

Study design

It is a prospective randomised multi-centre clinical study. In every medical centre each patient will be randomised for one of the operative procedures (Hoffman procedure vs soft tissue release). This will lead to two study groups, which will be compared.

Indications for surgery are: rheumatoid arthritis, pain, impaired mobility, dislocation and destructive changes of the MTP joints and after failure of conservative therapy after a duration of at least 6 months of therapy. After information and signing the informed consent form the patient will be included in the study.

Intervention

Surgery; one of the two methods:

1. Resection of the metatarsal heads (Hoffman's procedure)
2. Soft tissue release of MTP joints

Study burden and risks

The postoperative follow-up moments are at 3 months, 1 year and 5 year. Every outpatient visit of the included patient will have a duration of about 60 minutes. During these visits the patient will be interviewed, physically examined and the patient will have to fill out certain questionnaires. At 1 and 5 year postoperatively a X-ray of the foot will be performed. 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

Every cooperative patient with reumathoid arthritis, who has an indication for surgical intervention because of symptomatic MTP deformities (as defined in the protocol).

Exclusion criteria

- *Infected bursae/ clavi
- *Active reumathoid arthritis
- *Simultaneous surgical intervention of the foot, except for toe surgery
- *Certain comorbidity: arterial insufficiency, complex regional pain syndrome, diabetes mellitus, active infection

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):	20-04-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO	
Date:	18-02-2008
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
CCMO	NL15511.075.06