

Is there a difference in outcome between the Hoffman procedure and MTP-soft tissue-release in correcting reumatoid MTP-deformities?

No registrations found.

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

Summary

ID

NL-OMON25712

Source

NTR

Brief title

N/A

Health condition

Metatarsophalangeal (MTP) joint deformities
Reumatoid foot deformities
Hoffman procedure
MTP soft tissue- release

Dutch:

Metatarsophalangeaal (MTP) gewrichtsafwijkingen
Reumavoet-afwijkingen
Hoffman procedure
MTP soft tissue- release

Sponsors and support

Primary sponsor: Isala Clinics, Zwolle, The Netherlands

St Maartensclinic, Nijmegen, The Netherlands

Source(s) of monetary or material Support: Isala Clinics

Intervention

Outcome measures

Primary outcome

AOFAS-score (validated foot function score)

Secondary outcome

- Foot function index
- SF-36
- Complications
- VAS pain score
- Mobility score
- X-ray of foot

Study description

Background summary

The goal of this RCT is identifying the best surgical method in rheumatoid forefoot deformities, comparing the Hoffman procedure and MTP soft tissue- release. It is a multi centre study, involving 5 hospitals, with a follow up of 5 years.

Study objective

MTP-soft tissue- release has a better outcome in correcting rheumatoid MTP- deformities, compared to the Hoffman procedure

Study design

- Preoperative
- 2 weeks postoperative

- 6 weeks postoperative
- 3 months postoperative
- 1 and 5 years postoperative

Intervention

Two surgical procedures regarding the metatarsophalangeal joints in reumatic foot disorders:

1. Hoffman procedure
2. MTP- soft tissue release

Contacts

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Eligibility criteria

Inclusion criteria

Every patient suffering reumatoid arthritis, between 20 and 85 years old, with symptomatic MTP- deformities, as defined, with an indication for surgical intervention, not responding on conservative treatment during at least 6 months.

Exclusion criteria

1. Previous surgical intervention of toes
2. Infected bursae/ clavi
3. Active reumatoid arthritis
4. Simultaneous foot surgery; except for toe surgery
5. Specific comorbidity: insufficiency of arterial system, complex regional pain syndrome, diabetes mellitus, ongoing infection

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2008
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion	
Date:	27-10-2008
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	NL1459
NTR-old	NTR1520
Other	.0220 : 07
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

- Opinions on lesser toe deformities among Dutch orthopaedic departments. Foot Ankle Int. 2007 Dec;28(12):1265-70.

Schrier JC, Louwerens JW, Verheyen CC.

- The definitions of lesser toe deformities in literature. JAPMA, ahead of publication.

Schrier JC, Louwerens JW, Verheyen CC.