

'Evaluatie van MTP-1 artrodese en (hemi)prothese als behandeling van MTP-1 artrose met behulp van gangbeeld analyse'

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22662

Source

Nationaal Trial Register

Health condition

Hallux Rigidus, First Metatarsophalangeal joint, Osteoarthritis

Sponsors and support

Primary sponsor: N.A.

Source(s) of monetary or material Support: N.A.

Intervention

Outcome measures

Primary outcome

Range of Motion (ROM) of the hallux-forefoot segment, forefoot-hindfoot segment and hindfoot-tibia segment

Secondary outcome

- Spatiotemporal parameters (gait velocity, stride length, stride width, step length, step time, cadence, stance time)
- Plantar Pressure (Peak Pressure & Pressure Time Integral)
- Clinical Functioning/Outcome (AOFAS-HMI, VAS-pain, MOXFQ, FFI, SF-36)

Study description

Background summary

Despite the extensive literature on the surgical treatment of HR, no studies compared arthrodesis, hemiprosthesis and prosthesis as treatment options from an biomechanical point of view. The goal of this study is to find some clues in the gait pattern of patients with HR, which can help us in the future to predict which treatment option results in the best patient reported outcome in a patient-specific manner.

Study objective

We hypothesize that the range of motion of the hallux is limited during gait in patients with hallux rigidus (HR). In addition, we hypothesize that patients with HR will compensate this loss of motion of the hallux by increasing joint motion in the forefoot and hindfoot, in order to facilitate movement. Concerning plantar pressure, we expect a decreased pressure beneath the hallux with increased plantar pressure beneath the lesser metatarsals due to pain.

Study design

T1= prior to surgery

T2= one year after surgery

Intervention

- MTP1 arthrodesis
- MTP1 hemiprosthesis
- MTP1 prosthesis

Contacts

Public

Jasper Stevens
P. Debyelaan 25, P.O. Box 5800

Maastricht 6202 AZ
The Netherlands

Scientific

Jasper Stevens
P. Debyelaan 25, P.O. Box 5800

Maastricht 6202 AZ
The Netherlands

Eligibility criteria

Inclusion criteria

- Degenerative Hallux Rigidus, radiologically confirmed
- Failed conservative traject
- Able to walk more than 100 meters barefoot

Exclusion criteria

- Diabetes Mellitus
- Reumatoid Arthritis
- Gout
- Total Knee Prosthesis
- Total Hip Prosthesis
- Arthrodesis of another joint in the foot of interest
- Neurological condition resulting in an altered gait pattern

- Fractur(s) of bone(s) in the lower extremities resulting in an altered gait pattern

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-01-2015
Enrollment:	45
Type:	Anticipated

Ethics review

Positive opinion	
Date:	24-10-2017
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	NL6556
NTR-old	NTR6770
Other	17-N-14 : METC 14-4-080

Study results