First metatarsophalangeal joint arthrodesis vs implant arthroplasty; Prospective randomised clinical trial.

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

Summary

ID

NL-OMON39417

Source
ToetsingOnline

Brief title
DART

Condition

- Joint disorders

Synonym
hallux limitus, hallux rigidus, osteoartritis of the first metatarsophalangeal joint

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: lokaal fonds voor orthopedisch onderzoek

Intervention

Keyword: first metatarsophalangeal joint arthrodesis, Hallux rigidus, implant arthroplasty for the MTPI joint., osteoarthritis

Outcome measures

Primary outcome

* AOFAS-HMI score

* VAS pain score

* Satisfaction score

Secondary outcome

* X-ray evaluatie (anterior-posterior en lateraal)

o DMAA angle

o IMA angle

o lengte eerste metatarsaal

o Fusie in de arthrodesis groep

o Positie van hardware in de prothese groep

* SF-12 (dutch validated) quality of life score

* Gait analysis (Dynaport® device)

* voetdrukmeting (footscan® USB plate by RS International®)

* Lichamelijk onderzoek

o Range of motion van IP een MTPI

o Stbiliteit van gewricht

Study description

Background summary

The great toe is vital for normal, pain free ambulation. Osteoarthritis of the first metatarsal phalangeal joint (MTP I), also called hallux rigidus, leads to a painful great toe. Patients experience pain during ambulation, especially during the push-off phase of gait. When surgery is indicated, four techniques are widely used for hallux rigidus; cheilectomy, resection arthroplasty, arthrodesis and implant surgery.
Arthrodesis has been the hallmark for treatment of osteoarthrosis of the MTPI joint for active patients between 18 and 60 years of age because it maintains column stability of the first ray. Potential problems of arthrodesis include malunion, non-union and degeneration of the IP joint, although the clinical importance of IP arthritic changes has been debated. Many different techniques, with variable success, for achieving union of the MTPI arthrodesis have been described.
Endoprostetic implants are relatively new. Silicone implants like the arthroplasty developed by Swanson resulted in foreign body reactions and periarticulair bone loss. Subsequent implants, in particular the metallic hemiarthoplasty with or without polyethylene articulations, have been more successful. Still, implants are prone to wear of the material and show higher rates of infection compared to other techniques.
Arthrodesis of the MTPI-joint has shown its worth in the treatment of hallux rigidus. If positional requirements are met and fusion is achieved, this technique relieves patients of pain in the great toe. An even better biomechanical approach would be substituting the affected joint with a stable and long living implant. Thus far the longevity of a MTPI implant has been doubtful and its use controversial.

Study objective

The main objective of this study is to show the differences in outcome of two fundamentally different operational techniques in hallux rigidus. It will assess pain, range of motion and activity level in both groups using the standardised AOFAS-HMI score as well as a VAS pain score. This score has a maximum of 100 points for a patient feeling no pain, having a full range of motion and full stability of both the MTPI joint and the IP joint while experiencing no limitations in activities.
Secondary objectives are biomechanical assessments of the two groups of patients, both before and after operation, by measurement of foot pressure during gait and a 24 hours gait analysis. Furthermore complications, (sports)activities, quality of life and satisfaction with the treatment will be recorded. Radiological angles of the hallux position, union of the arthrodesis and osteolytic appearance of the bone will be recorded.

Study design

Prospective randomised multi-centre comparative clinical trial with intention to treat principle.

Intervention

1. Arthrodesis of the MTPI joint.

or

2. Implantation of a MTPI prosthesis.

Study burden and risks

The burden for patients consist mainly of the fact that they will not know wich operation will be performed untill the operation itself. They were already considered for operative treatment so no extra burden lies within the operation itself. Patients follow-up will take up some more of their time for answering the questionnaires and participation in the movementmeasurements

Risks for the patients are the same if they did not cooperate in this study since they would have been treated with one of the operational techniques.

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

MTPI degenerative arthritis stage II or III

Exclusion criteria

Diabetes
neurogenic disorders
age above 70 years

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL25414.094.08