Triple arthrodesis of the hindfoot: a long-term prospective outcome study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON42332

Source
ToetsingOnline

Brief title
Triple 15 years

Condition

- Bone and joint therapeutic procedures

Synonym
arthrodesis; fusion of hindfoot

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Anna Fonds

Intervention

Keyword: ankle osteoarthritis, hindfoot, long-term results, triple arthrodesis

Outcome measures

Primary outcome

The main study outcome is the level of OA graded with the Kellgren and Lawrence score on an X-rays of the ankle and foot.

Secondary outcome

The Meary*s angle will be measured to evaluate the bony alignment of the foot. Standardized digital photos will be made to assess the geometry/alignment. Additionally, with two questionnaires, the Foot Function Index (FFI) and the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot score, the clinical outcome will be investigated.

Study description

Background summary

Triple arthrodesis is an operative salvage procedure for treatment of painful, deformed and/or unstable tarsal joints. However, debate exists regarding the effect of triple fusion on the development of osteoarthritis (OA) of the ankle joint. Since, triple arthrodesis is a technical difficult procedure and correction of the shape/alignment of the foot may be not as adequate as intended, malalignment might persist after operative correction. Malalignment may be more important in determining OA of the ankle than the fusion itself. The hypothesis is that after a mean follow up time of 15 years, the geometry and subjective outcome would remain improved. Compared with the earlier evaluation (at 2 and 7.5 years), an increase of OA of the ankle joint is expected. More specific, the increase of OA is expected to be mild and associated with pre-existing OA of the ankle joint and/or associated with persistent malalignment of the foot after triple fusion.

Study objective

The objective of the present study is to investigate the long-term effect (15 years follow-up) of triple arthrodesis on the ankle joint and the development of secondary OA of the ankle joint. Additionally, alignment and clinical outcomes will be examined.

Study design

This follow-up study is a prospective cohort study

Study burden and risks

Patients are asked to visit our clinic once. The extra amount of time that a patient invests in the study is about 1 hour. Prior to the visit the patients are asked to fill in a questionnaire (FFI), during the visit X-rays and digital photos of the ankle/foot will be taken and the physician will perform a physical examination (AOFAS). The questionnaires and physical examination of the foot do not bring any extra burden. The additional radiological assessment has a radiation amount of 0.001 mSv and is minimal compared with the natural radiation of 2 mSv per year.

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

Patients who underwent a triple arthrodesis in the period 1999 to 2002 in the Sint Maartenskliniek

Exclusion criteria

Not signing informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2015
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	27-08-2015

Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL53881.048.15

Study results

Date completed:	28-01-2016
Actual enrolment:	35