Subtalar arthrodesis for post-traumatic osteoarthritis after intra-articular calcaneal fractures

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

Summary

ID

NL-OMON37636

Source
ToetsingOnline

Brief title
Subtalar arthrodesis after calcaneal fractures

Condition

- Bone and joint injuries
- Fractures
- Bone and joint therapeutic procedures

Synonym
Heel bone fracture. Joint degeneration.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Calcaneal fracture, Post-traumatic arthritis, Subtalar arthrodesis

Outcome measures

Primary outcome

1. Clinical outcome:

* American Orthopaedic Foot and Ankle Society Hindfoot Score

* Foot and Ankle Outcome Score

* Physical examination foot

2. Radiological assessment:

* Talocalcaneal alignment and dimension

* Arthrodesis union

* Adjacent joint arthritis

3. Dynamic gait analysis

Secondary outcome

None

Study description

Background summary

Despite progresses in surgical treatment and outcome of intra-articular calcaneal fractures, up to 16% of patients require late subtalar joint arthrodesis to alleviate painful posttraumatic osteoarthritis. There is however limited literature on subtalar arthrodesis following operative treatment of calcaneal fractures. Specifically, it is unknown whether this procedure results in adequate pain improvement without progressive adjacent joint arthritis, reversal of pathological gait pattern, correction of any talocalcaneal misalignment, and finally, satisfying clinical and functional outcome.

Study objective

The primary objective is to evaluate clinical hindfoot outcome (e.g. pain, function, alignment) in patients that underwent subtalar joint arthrodesis due to painful post-traumatic subtalar joint osteoarthritis following operative treatment of an intra-articular calcaneal fracture.
We hypothesize that subtalar joint arthrodesis results in painless, satisfying hindfoot function.
Secondarily, the radiological outcome and dynamic gait pattern will be evaluated, by comparing the affected foot to the unaffected contralateral side.

Study design

Follow-up case series

Study burden and risks

Patient burden/risk:

On participation, the patient will visit the outpatient department once (half a day), for:
* Conventional radiology (total radiation 0.006 Msv, therefore minimal risk)
* Dynamic foot analysis (no risk)
* Questionnaire completion and physical examination foot (no risk)

Patient benefit:
* Re-examination of operated foot
* Possibility to address symptoms/problems
* Possibility to initiate treatment if necessary

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

* Age > 18 years
* Informed consent
* Displaced intra-articular calcaneal fractures (Sanders type II, III and IV)
* Initial open reduction and internal fixation by using the extended lateral approach
* Isolated subtalar arthrodesis

Exclusion criteria

* Calcaneal fractures involving solely the anterior process or pure beak fractures
* Initial conservative treatment or primary arthrodesis of the calcaneal fractures
* Other than extended lateral approach
* Pantalar or triple arthrodesis in the case of arthrodesis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2013
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2012
Application type:	First submission
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	NL40390.018.12