Functional and Radiological Outcome after Distal Tibiofibular Arthrodesis for Chronic Instability

Published: 18-11-2011
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With this study we will try to assess the positive and negative aspects with radiological and functional tests.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON35599

Source
ToetsingOnline

Brief title
Distal tibiofibular arthrodesis

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Synostosis / distal tibiofibular arthrodesis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ankle, syndesmotic instability, Synostosis, tibiofibular joint

Outcome measures

Primary outcome

Functional assessment

- AOFAS ankle scores, American Orthopaedic Foot & Ankle Society (AOFAS)

ankle-hindfoot clinical rating scale

- Foot Ankle Ability Measure (FAAM)

- Foot and Ankle Outcome Score (FAOS)

Radiological assessment

- arthritis scores (van Dijk et al./ Kellgren and Moore / etc.)

Secondary outcome

Perceived disability as quantified by the following scoring system:

- SF-36

- Range of motion

- Patient overall satisfaction with the outcome of the procedure on a NRS

- Complications

- Re-operations

- Adverse events

Study description

Background summary

Literature regarding dong term outcome of distal tibiofibular arthrodesis in patients with chronic ankle instability is scarce.

Study objective

With this study we will try to assess the positive and negative aspects with radiological and functional tests.

Study design

retrospective case series

Study burden and risks

- 1 visit to the outpatient clinic (20 min.)
- 2 radiographs of the treated ankle (0.001 mSv per radiograph, max 0,004 mSv in total)
- 3 questionnaires (AOFAS, FAAM, FAOS)

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients: >18 years
All patients who were treated with a distal tibiofibular arthrodesis (creation of a synostosis) for chronic syndesmotic instability (more than 6 months after initial trauma).

Exclusion criteria

Patients younger than 18 years at time of follow up.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	11
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-11-2011

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	NL37480.018.11