

Lange termijn resultaten na een enkelartrodese

No registrations found.

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

Summary

ID

NL-OMON23848

Source

NTR

Health condition

ankle arthrodesis, arthritis, artrodese, arthrodesse, enkel, artrose

Sponsors and support

Primary sponsor: Erasmus Medical Center, Department of Orthopaedics

Source(s) of monetary or material Support: Internal funding

Intervention

Outcome measures

Primary outcome

Degree of arthritis in de adjacent joints (subtalar joint and talonavicular joint) in patients that have had an ankle arthrodesis

Secondary outcome

(1) the amount of increase of arthritis in the adjacent joints compared to before surgery, (2) the degree of arthritis in the contralateral ankle, (3) the correlation between degree of arthritis and patient reported outcomes

Study description

Background summary

Rationale: In patients with end-stage ankle arthritis, an ankle arthrodesis is a common surgical procedure for pain relief. Due to changed biomechanical loading after an ankle arthrodesis, patients might be at increased risk of adjacent joint degeneration. However, the long term effects of an ankle arthrodesis are still largely unknown.

Objective: The main aim of this study is to investigate if patients that received an ankle arthrodesis, have arthritis in the adjacent joints (subtalar joint and talonavicular joint). Furthermore, we would like to study (1) the amount of increase of arthritis in the adjacent joints compared to before surgery, (2) the degree of arthritis in the contralateral ankle, (3) the correlation between degree of arthritis and patient reported outcomes.

Study design: Observational study

Study population: Patients that underwent an ankle arthrodesis in the Erasmus MC at the department of Orthopaedics since 1-1-2004 until 31-12-2016.

Main study parameters/endpoints: The main study outcome is the degree of arthritis in the subtalar joint and talonavicular joint, scored with the Kellgren and Lawrence score based on a CAT-scan.

Study objective

Patients that have had an ankle arthrodesis will develop arthritis in the adjacent joints after the ankle arthrodesis

Study design

Patients will be invited to visit the Erasmus MC for one follow-up appointment. The time between the ankle arthrodesis and follow-up appointment will vary from 2 to 15 years.

Intervention

This is an observational study in which patients that have had an ankle arthrodesis will be asked to visit the Erasmus MC for a follow-up visit. During this follow-up visit a bilateral CAT-scan of the ankle and an X-ray will be made. Also patients will be asked to fill out questionnaires and will be physically checked by Orthopedic surgeon.

Contacts

Public

A. Willems
Rotterdam
The Netherlands

Scientific

A. Willems
Rotterdam
The Netherlands

Eligibility criteria

Inclusion criteria

- Received a primary ankle arthrodesis at the department of Orthopaedics of the Erasmus MC between 1-1-2004 until 31-12-2016
- A pre-operative CAT-scan of the operated ankle is available

Exclusion criteria

- Received a double or triple arthrodesis
- Arthrodesis with an intramedullary nail or external fixator
- Amputation of the ankle after the arthrodesis
- Patient deceased

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2018
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion	
Date:	11-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46392
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7331
NTR-old	NTR7547
CCMO	NL65370.078.18
OMON	NL-OMON46392

Study results