

# Follow-up of patients with an ankle arthrodesis

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Joint disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON46392

### Source

ToetsingOnline

### Brief title

Follow-up of patients with an ankle arthrodesis

### Condition

- Joint disorders

### Synonym

ankle fusion, arthrodesis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Afdeling

## Intervention

**Keyword:** Ankle arthrodesis, Arthritis, Follow--up

## Outcome measures

### Primary outcome

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.

### Secondary outcome

Degree of increase of arthritis in the adjacent joints between pre-operative CAT-scan and follow-up CAT scan.

Degree of arthritis in adjacent joint in the ankle with the ankle arthrodesis compared to the contralateral ankle

Correlation between patient reported outcomes and degree of arthritis of the adjacent joints.

## Study description

### Background summary

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. Several studies showed, that patients with an ankle arthrodesis do have arthritis in the adjacent joints. However, most of those studies do not report preoperative arthritis grade. Therefore, it remains unclear if arthritis of the adjacent joints is a consequence of the arthrodesis or if it was already existing before the arthrodesis. Only few studies compared the amount of arthritis before the arthrodesis to the amount of arthritis after the arthrodesis. Interestingly, those studies reported that in most patients with adjacent joint arthritis, the arthritis was already pre-existing before the ankle arthrodesis. Hendrickx et al. 2011 reported that progression of

osteoarthritis in adjacent joint is likely after an ankle arthrodesis, but that it becomes rarely symptomatic. Overall, as has been described in the review of Ling et al., a paucity of studies evaluate the preoperative prevalence of adjacent joint arthritis and therefore it is still unclear if an ankle arthrodesis increases the risk of adjacent joint arthritis.

## **Study 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 burden and risks**

Patients will visit the outpatient clinic of the department of Orthopaedics of the Erasmus MC for a bilateral CAT-scan, x-rays, physical examination of the ankle and to fill in questionnaires. This will take approximately 1 hour. These are all standard clinical scans and test, and patients will not be exposed to any risks.

## **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

Patient has had ankle arthrodesis in the Erasmus MC at the department of orthopedics between 2004 and 2017, a pre-operative CAT-scan 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 invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated):	03-04-2019
Enrollment:	30
Type:	Actual

## Ethics review

Approved WMO	
Date:	09-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23848  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL65370.078.18
OMON	NL-OMON23848