

# Post-traumatic osteoarthritis and function after surgery of trimalleolar fractures: is the function on medium follow-up period predictive for the long term follow-up period?

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Determination of post-traumatic osteoarthritis in patients with a short follow-up period after ankle-surgery.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Fractures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON39723

### Source

ToetsingOnline

### Brief title

MILAN

### Condition

- Fractures

### Synonym

ankle fracture, Fracture of posterior malleolus, trimalleolar fracture

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Medisch Centrum Haaglanden

**Source(s) of monetary or material Support:** Eigen financiering van maatschap Heelkunde

## Intervention

**Keyword:** fixation technique, posterior malleolus, post-traumatic osteoarthritis, trimalleolar fractures

## Outcome measures

### Primary outcome

Artrosis of the ankle, classified according to the AO-scale.

### Secondary outcome

Function

Questionnaire: AOFAS-, AAOS-, VAS-scale

## Study description

### Background summary

Post-traumatic osteoarthritis in trimalleolar fractures are, according to the most publications, a matter of long term. Osteoarthritis is a slow proces, therefore we think that early damage according to a trimalleolar fracture will be visible on short term. This is supported by our clinical findings of early osteoarthritis on different patients 4,5 years after ankle surgery.

### Study objective

Determination of post-traumatic osteoarthritis in patients with a short follow-up period after ankle-surgery.

### Study design

Patients with ankle-surgery of a trimalleolar fracture between 2008 and 2010 will be recalled back to the hospital and two new X-ankles will be made. They will also answer a questionnaire (AOFAS, AAOS, VAS) and will undergo a

review of the ankle by the observer.

### **Study burden and risks**

The risk of damage by radiation is very small. The dose will be even smaller than 1% of the year-dose-background-radiation in the Netherlands. So this risk will be negligible small.

## **Contacts**

### **Public**

Medisch Centrum Haaglanden

Berberisstraat 33  
Den Haag 2565 WT  
NL

### **Scientific**

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NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Persons with a trimalleolar fracture in their history, operative treatment of the ankle between 01-01-2008 and 31-12-2010.

## Exclusion criteria

Reumatoid Artrosis  
an other ankle fracture of the same leg  
invalidity

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-02-2013

Enrollment: 50

Type: Actual

## Ethics review

Approved WMO

Date: 23-01-2013

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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**

<b>Register</b>	<b>ID</b>
CCMO	NL41805.098.12