

# Follow-up of a randomized controlled trial comparing closing-wedge and opening-wedge high tibial osteotomy for medial compartment osteoarthritis of the knee.

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To study the radiological and clinical long term results as well as the survival rate in participants of our randomized controlled trial comparing opening- and closing-wedge osteotomy ten and fifteen year post-operatively.

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

## Summary

### ID

NL-OMON37143

### Source

ToetsingOnline

### Brief title

Follow-up of a RCT comparing closing and opening-wedge HTO

### Condition

- Joint disorders

### Synonym

multifactorial chronic joint disease, osteoarthritis

### Research involving

Human

## Sponsors and support

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

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

## Intervention

**Keyword:** closing wedge, follow-up, high tibial osteotomy, opening wedge

## Outcome measures

### Primary outcome

Functional outcomes: change in severity of pain (Visual Analogue Scale; VAS), the intermittent and constant pain score; ICOAP, Knee injury and Osteoarthritis Outcome Score (KOOS), Hospital for Special Surgery scale (HSS)

### Secondary outcome

1. Complications and re-operations
2. Medial and lateral collateral ligamentous stability
3. Loss of correction measured with hip-knee-ankle- angle (HKA-angle)
4. Radiological progression of osteoarthritis
5. Patient satisfaction

## Study description

### Background summary

We conducted a RCT in which we compared closing-wedge vs opening-wedge high tibial osteotomy (HTO). (MEC 196.813/2000/232)

There is a lack of radiological and clinical long term results of well designed prospective studies comparing closing-wedge and opening-wedge HTO. To study the results of these techniques on the long term, we aim to re-examine the participants of this RCT ten and fifteen year postoperatively.

### Study objective

To study the radiological and clinical long term results as well as the survival rate in participants of our randomized controlled trial comparing opening- and closing-wedge osteotomy ten and fifteen year post-operatively.

## **Study design**

Long-term follow-up of a Randomized Controlled Trial comparing closing-wedge HTO and opening wedge HTO with identical postoperative care. Closing-wedge HTO was fixed with staples and opening-wedge HTO with a Puddu-plate. Patients who underwent total knee arthroplasty (TKA) during follow-up will be asked to give permission to review their last pre-TKA radiographs. Patients who did not undergo TKA will be asked to fill in 3 questionnaires (general questionnaire, Knee Osteoarthritis Outcome Score, Visual Analogue Score-pain and Intermittent and Constant Pain Score), to visit the department of Orthopaedics for physical examination and three radiographs will be made; whole leg radiograph, lateral and posteroanterior view of the knee.

## **Intervention**

Index group: opening wedge osteotomy  
Control group: closing wedge osteotomy

## **Study burden and risks**

The burden is primarily time (outpatient clinic visit and questionnaires) and radiation (three radiographs; whole leg radiograph, lateral and posteroanterior view of the knee). There is no direct benefit from participation. Travel allowance will be offered to participants.

## **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

All patients included in our Randomized Controlled Trial between January 2001 and January 2004.

### Exclusion criteria

None

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	11-03-2013
Enrollment:	92
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-12-2012
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

No registrations found.

### In other registers

Register	ID
CCMO	NL42516.078.12