

# Accuracy of achieved correction of open versus closed wedge high tibial osteotomies, with locking plate fixation.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25898

### Source

NTR

### Brief title

HTO-trial

### Health condition

Medial compartment osteoarthritis of the knee

## Sponsors and support

**Primary sponsor:** Erasmus Medical Center, Department of Orthopaedics

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

## Intervention

## Outcome measures

### Primary outcome

Comparison of the accuracy of achieved correction of the mechanical axis in the frontal plane relative to preoperative planning endeavouring to achieve 3-4 degrees of valgus between open and closed HTO's measured on a whole leg radiograph.

Timepoint: 6 weeks postoperatively

## **Secondary outcome**

1. Functional outcomes: change in pain severity (Visual Analogue Scale; VAS), Knee injury and Osteoarthritis Outcome Score (KOOS), Hospital for Special Surgery scale (HSS);
2. Complications;
3. Medial and lateral collateral ligamentous stability;
4. Change in Bone Mineral Density, measured by DXA scan, of medial and lateral compartments, with the Regions Of Interest (ROI's) being in the tibia plateau;
5. Loss of correction;
6. Change of tibial slope;
7. Change of patellar height;
8. Plate irritation;
9. Patient satisfaction.

## **Study description**

### **Background summary**

A valgus high tibial osteotomy is one of the treatment modalities for people with severe unicompartimental osteoarthritis of the knee with varus malalignment. Besides the open wedge, is the closed wedge HTO a frequently used technique. A previous RCT showed that closed wedge osteotomy gave a more accurate correction. There was a loss correction in some cases in the open wedge HTO-group caused by instability of the lockingplate. Locking plate fixation has led to improved stability when used in open and closed HTO.

An open wedge high tibial osteotomy (HTO) is thought to allow more accurate adjustment of the attained tibial correction.

The findings of this study will show us which technique is superior for correction of the mechanical axis.

We expect that an accurate correction of the mechanical axis of the knee, without loss of correction, will have a positive effect on the clinical results of this procedure.

## Study objective

An open wedge high tibial osteotomy (HTO) is thought to allow more accurate adjustment of the attained tibial correction.

## Study design

Preoperatively, 6 weeks, 12, 24 and 60 months postoperatively.

## Intervention

Open and closed wedge HTO's, both using locking plate fixation and with identical postoperative care.

## Contacts

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## Eligibility criteria

### Inclusion criteria

1. Age between 18-65 years;
2. Knee pain located over the medial tibiofemoral compartment;
3. Kneepain  $\geq$  3 months;

4. VAS > 20 mm;
5. K&L grade I-III;
6. Varus malalignment measured on a whole leg radiograph (<12 degrees).

## Exclusion criteria

1. OA of the lateral compartment;
2. Grade III collateral ligament laxity;
3. ROM < 100 degrees;
4. Flexion contracture > 10 degrees;
5. History of fracture or previous open operation of the lower limb;
6. Rheumatoid arthritis;
7. Contralateral HTO;
8. Insufficient command of the Dutch language, spoken and/ or written.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2012
Enrollment:	124

Type: Anticipated

## Ethics review

Positive opinion

Date: 05-07-2012

Application type: First submission

## Study registrations

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

ID: 34209

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL3358
NTR-old	NTR3506
CCMO	NL32423.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34209

## Study results

### Summary results

N/A