# Closing wedge high tibial osteotomy for unicompartmental knee osteoarthritis: staples and cast fixation versus TomoFix plate fixation a randomised trial

Submission date 27/01/2006	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 13/06/2014	<b>Condition category</b> Musculoskeletal Diseases	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

### Plain English summary of protocol

Not provided at time of registration

## **Contact information**

#### **Type(s)** Scientific

Sciencinc

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### **Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2; NTR483

## Study information

Scientific Title

Acronym Closing HTO

### **Study objectives**

Closing wedge osteotomy with plate fixation only will result in earlier mobilisation and better 1year results considering pain and function then staple and cast fixation.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Received from the local medical ethics committee

**Study design** Randomised active controlled parallel group trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

**Participant information sheet** Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied Arthritis, osteoarthritis

**Interventions** Closing wedge high tibial osteotomy: staples and cast fixation versus TomoFix plate fixation.

**Intervention Type** Other

**Phase** Not Applicable

#### Primary outcome measure

Is the accuracy of achieved correction of the mechanical limb axis post-operatively compared to the pre-operatively planned correction superior for closing wedge HTO with plate fixation?

Measurement:

Conservation of corrected angular limb deformity 1 year after surgery (success rate [%]). (Surgery is successful when the femoral-tibial axis 1 year after osteotomy is corrected accurately two degrees or less compared to the preoperative planned mechanical axis correction.)

### Secondary outcome measures

1. Does the functional outcome differ between the two bone defect implants? Measurement:

- 1.1. Knee range of motion (ROM)
- 1.2. Pain score (Visual Analogue Scale)
- 1.3. Hospital for Special Surgery (HHS) Knee Service Rating System
- 1.4. Western Ontario and McMaster University Osteoarthritis Index (WOMAC)
- 1.5. Health-related quality-of-life score (EuroQol)
- 1.6. Complication
- 2. Which surgical technique is most efficient? Measurement: cost efficiency

### Overall study start date

01/08/2004

### **Completion date**

31/12/2007

## Eligibility

### Key inclusion criteria

1. Patients (male and female) with symptomatic medial osteoarthritis of the knee who are not indicated for a knee arthroplasty

- 2. Above 18 years of age
- 3. Patient is knowledgeable and able to understand the treatment consequences
- 4. Informed consent

Participant type(s)

Patient

**Age group** Adult

**Lower age limit** 18 Years

**Sex** Both

**Target number of participants** 92

Key exclusion criteria

1. Mechanical axis not through the medial compartment (HipKneeAnkle angle greater than 180 degrees)

2. Rheumatoid arthritis

3. HipKneeAnkle angle less than 169 degrees

4. Range of motion (ROM) less than 100 degrees

5. Extension deficit 15 degrees

6. Collateral ligament insufficiency (instability grade 3)

7. Indication for a supracondylar femur osteotomy

8. Not able to speak or understand Dutch

Date of first enrolment 01/08/2004

Date of final enrolment 31/12/2007

## Locations

**Countries of recruitment** Netherlands

**Study participating centre Erasmus University Medical Centre** Rotterdam Netherlands 3000 CB

## Sponsor information

**Organisation** Erasmus Medical Centre (The Netherlands)

**Sponsor details** Dr. Molewaterplein 40/50 Rotterdam Netherlands 3000 CA

**Sponsor type** Hospital/treatment centre

Website http://www.erasmusmc.nl/content/englishindex.htm

### ROR

https://ror.org/018906e22

## Funder(s)

Funder type Not defined

**Funder Name** Not provided at time of registration

## **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Not provided at time of registration