

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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 1-year 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

Primary study design

Interventional

Study design

Randomised active controlled parallel group trial

Study type(s)

Treatment

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(s)

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.)

Key secondary outcome(s)

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 (HSS) 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration