ISRCTN32133423 https://doi.org/10.1186/ISRCTN32133423

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 [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 13/06/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr T M van Raaij

Contact details
Erasmus University Medical Centre
Department of Orthopaedic Surgery
P.O. Box 2040
Rotterdam
Netherlands
3000 CB

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 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

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