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Demineralised bone matrix (DBM) as an alternative for autogenous bone graft in high tibial valgus opening wedge osteotomy (HTO) for symptomatic medial compartmental knee osteoarthritis

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 03/11/2008	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1; NTR478

Study information

Scientific Title

Study objectives
Opening wedge HTO treated with DBM will better match one year post-operative mechanical axis alignment with pre-operative planned correction than opening wedge HTO filled with autogenous iliac crest bone.

Ethics approval required
Old ethics approval format

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

Study design
Multicentre, randomised active controlled factorial trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
A valgus high tibia opening wedge osteotomy will be performed and the osseous defect will be filled with DBM or autogenous bone graft.

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
1. Knee range of motion (ROM)
2. Pain score (Visual Analogue Scale)
3. Hospital for Special Surgery (HHS) Knee Service Rating System
4. Western Ontario and McMaster University Osteoarthritis Index (WOMAC)
5. Health related quality-of-life score (EuroQol)
6. Donor site complication (only autogenous bone graft group)

Overall study start date
01/10/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Male and female
2. Symptomatic medial osteoarthritis of the knee
3. Not indicated for a knee arthroplasty
4. Informed consent given
5. Baseline measurements are made

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Below 18 years of age
2. Symptoms not related to medial osteoarthritis of the knee
3. Not able to speak or understand Dutch

Date of first enrolment
01/10/2005

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