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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22408

Source
NTR

Brief title
N/A

Health condition

a prospective randomized trial

Intervention

Outcome measures

Primary outcome

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

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)donor site complication (only Group autogenous bone graft).

Study description

Study objective

Opening wedge HTO treated with DBM will better match one year post-operative mechanical axis alignement with pre-operative planned correction then opening wedeg HTO filled with autogenous iliac crest bone.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Exclusion criteria are below 18 years of age, symptoms not related to medial osteoarthritis of the knee or not able to speak or understand Dutch.
Patients will be included after informed consent given and baseline measurements made.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2005

Enrollment:	80
Type:	Actual

Ethics review

Positive opinion Date:	15-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL438
NTR-old	NTR478
Other	: 1
ISRCTN	ISRCTN76261748

Study results

Summary results
High tibia osteotomy for osteoarthritis of the knee: a prospective randomized trial

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