

Should a patient with medial knee osteoarthritis be operated?

Published: 24-01-2014

Last updated: 15-05-2024

A high tibial osteotomy is an effective intervention to treat patients with clinical complaints of medial knee osteoarthritis (superiority study) compared to an orthopaedic unloader knee brace.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON27146

Source

NTR

Brief title

BVO Trial

Condition

- Joint disorders

Synonym

knee osteoarthritis

Health condition

Knee pain; Knee osteoarthritis; Mediale gonartrose

Research involving

Human

Sponsors and support

Primary sponsor: ReumaNederland

Source(s) of monetary or material Support: Reumafonds

Intervention

- Surgical procedure

Explanation

Outcome measures

Primary outcome

knee pain after one year of follow-up

Secondary outcome

1. Patient Reported Outcomes: pain severity, function, quality of life, physical activity and patient satisfaction; 2. Change in structural features with respect to cartilage and subchondral bone; 3. Adverse events; 4. Pain medication use; 5. Direct and indirect costs.

Study description

Background summary

Rationale: To postpone joint replacement surgery for patients with uni-compartment osteoarthritis an osteotomy surgery or an unloader kneebrace are effective treatment options. Till date the effect on symptoms and structural progression of this non-surgical knee brace with the surgical osteotomy has not been compared. Objective: To assess the effects on pain, function, quality of life and structural features with respect to cartilage and subchondral bone of osteotomy surgery after one year of follow-up compared to the effects of treatment with an orthopaedic un-loader knee brace. Study population: Patients, age 18-60, with isolated medial compartment osteoarthritis, concomitant with a varus mechanical axis of the knee, good range of motion and limited ligamentous knee laxity. Intervention: A Randomized Control Trial comparing osteotomy surgery with an orthopaedic un-loader knee brace. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden is primarily time (visit of outpatient clinic, and to fill in questionnaires). There is no direct benefit from participation or group relatedness. Osteotomy and non-surgical treatment with an un-loader knee brace are both options in the standard care of active patients, younger than 65, with medial compartment osteoarthritis of the knee.

Study objective

A high tibial osteotomy is an effective intervention to treat patients with clinical complaints of medial knee osteoarthritis (superiority study) compared to an orthopaedic unloader knee brace.

Study design

Baseline, 3, 6, 9, 12 and 24 months

Intervention

- 28 patients will receive a high tibial osteotomy - 28 patients will receive an unloader brace

Contacts

Public

Erasmus Medical Center, Department of General Practice,
P.O. Box 1738
S. Bierma-Zeinstra
Rotterdam 3000 DR
The Netherlands
+31 (0)10-4087633

Scientific

Erasmus Medical Center, Department of General Practice,
P.O. Box 1738
S. Bierma-Zeinstra
Rotterdam 3000 DR
The Netherlands
+31 (0)10-4087633

Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

- age 18 - 65 - medial knee pain > 3 months - NRS score > 3 - radiographic signs of medial knee osteoarthritis - varus malalignment > 0° en ≤14°

Exclusion criteria

- Lateral compartment with Kellgren & Lawrence \geq grade 2 - contraindication to one of the two interventions - rheumatoid arthritis - grade-3 collateral ligament laxity - a flexion contracture of $> 10^\circ$ - range of motion of $< 100^\circ$ - fracture or previous open operation of the lower limb - patients with a contralateral high tibial osteotomy will be excluded if the first knee has been included in this trial - patients that already used an orthopaedic knee brace for knee OA in the same knee - patients from whom it is not sure that they will be able to attend the follow-up measurements - insufficient command of the Dutch language, spoken and/or written

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2014
Enrollment:	124
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date: 13-01-2014
Application type: First submission
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

ID: 44769
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4200
NTR-old	NTR4411
CCMO	NL45685.078.13
OMON	NL-OMON44769

Study results