Should a patient with medial knee osteoarthritis be operated? A RCT

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To assess the effects on knee pain, function, quality of life and change in 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...

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

Summary

ID

NL-OMON44769

Source
ToetsingOnline

Brief title
Should medial knee OA be operated?

Condition

- Joint disorders

Synonym
arthrosis, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: knee osteoarthritis, osteotomy, RCT, unloader brace

Outcome measures

Primary outcome

The primary endpoint of the study is the knee pain after one year of follow-up assessed with the pain subscale of the Knee injury and Osteoarthritis Outcome Score.

Secondary outcome

Secondary endpoints in the study are difference in the following outcome parameters: pain severity (Numerical Rating scale; NRS), other KOOS subscales, Hospital for Special Surgery scale (HSS), quality of life (EQ5-D), and physical activity scores (SQUASH). Other outcomes are pain medication use, side effects, difference in direct and indirect costs (PRODISC), change in cartilage quality of the medial and lateral compartment of the tibia (semi-quantitative and quantitative MRI scores), changes of bone mineral density of the medial and lateral compartment of the tibia (DXA scan), mechanical axis of the limb (whole leg radiographs) and serum and urine (osteoarthritis biomarker, genetic profile) will be collected and bone remodelling activity (SPECT CT scan).

Study description

Background summary

To postpone joint replacement surgery for patients with uni-compartiment 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.

Study objective

To assess the effects on knee pain, function, quality of life and change in 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 design

In this open-labeled study; patients will be randomized in group (a) treatment with an orthopaedic un-loader knee brace; or in group (b) a high tibial osteotomy will be performed. The recruitment period will be maximal 1,5 year and the total follow up period will be 2 years (with a primary outcome at one year follow-up).

Intervention

Patients will be randomized in group (a) treatment with an orthopaedic un-loader knee brace; or in group (b) a high tibial osteotomy.

Study burden and risks

A disadvantage of study participation is that the outpatient clinic visits will ask additional time of the patient. The patient has to fill in a number of questionaires. One additional whole leg radiograph will be made (12 months). Also three DXA scans will be made (start study, and after 12 and 24 months) to assess the bone mineral density. Finally two MRI of the knee will be made (start study and after 12 months). Serum and urine will be collected at start of the study and after 12 months. SPECT CT scan (baseline and after 12 months) will be performed in patients who give additional informed consent.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

knee pain located over the medial tibiofemoral compartment of the knee, knee pain for more than 3 months, with a severity of the knee pain of 3 on a NRS score or higher (range 0 to 10), radiographic signs of medial knee OA, defined by a Kellgren & Lawrence score of grade 1 or higher, and presence of varus malalignment as measured on a whole leg radiograph.

Exclusion criteria

OA of lateral compartment, rheumatoid arthritis, grade-3 collateral ligament laxity, range of motion of < 100°, a flexion contracture of > 10°, history of fracture or previous open operation of the lower limb, patients that already used a orthopaedic knee brace for knee OA in the same knee, patients with a contralateral high tibial osteotomy will be excluded if the first knee has been included in this trial; thus, if both knees are symptomatic, only the first knee will be included, 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 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

Ethics review

Approved WMO Date:	13-01-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-07-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-09-2015
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-03-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27146
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45685.078.13
OMON	NL-OMON27146