Joint distraction (KJD) in treatment of knee osteoarthritis: a comparison with a presently applied surgical alternative: high tibial osteotomy (HTO)

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Ethical review	Not approved
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON34414

Source
ToetsingOnline

Brief title
Knee joint distraction compared to high tibial osteotomy

Condition

- Autoimmune disorders
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
joint degeneration, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: Cartilage repair, Distraction, Knee, Osteoarthritis

Outcome measures

Primary outcome

1. Intrinsic cartilage repair, examined as decrease in 'denuded area's of bone', as determined on quantitative MRI in comparison with own baseline values and with HTO.

Secondary outcome

2. Cartilage tissue repair over 2 year follow-up compared to baseline by use of queantitative MRI parameters of the same iamges, X-ray evaluation, and biomarker analyses in blood and urine.

3. Clinical effetiveness determined by a questionnaire for pain, other symptoms, function in daily living, function in sports and recreation, and knee related quality of life (KOOS) and a VAS for pain.

4. Indication of costs-effeciveness.

Study description

Background summary

Knee Joint Distraction (KJD) is proven to be beneficial in patients with endstage osteoarthritis of the knee in comparison with their own baseline profile. Following, this experimental procedure will be compared with currently used surgical techniques in treatment of osteoarthritis of the knee, namely high tibial osteotomy (HTO). It is expected that KJD result in (more) intrinsic

cartilage repair and has equivalently or better clinical outcome.

Study objective

1. To compare cartilage repair between KJD and HTO, evaluated 2 years post treatment. The hypothesis is that KJD results in (more) cartilage repair compared to HTO.

2. To compare cartilage tissue repair over 2 year follow-up compared to baseline and between treatments by use of (additional) quantitative MRI parameters of the same images, as well as X-ray evaluation, and analyses of serum and urine biochemical markers of cartilage turnover.

3. To describe and compare the clinical efficacy over 2 years of treatment by a questionnaire (KOOS; for pain, other symptoms, function in daily living, function in sports and recreation, and knee related quality of life) and by a VAS for pain.

4. To gather preliminary data on medical consumption and non-medical costs related to disease and treatment as well as quality of life.

Study design

This, single site, randomised controlled, unblinded 2 years follow-up trial will be accomplished at the Maartenskliniek Woerden (MK-W). Patients with severe unicompartimental OA of the knee, for whom conservative therapy fails and are indicated for a HTO by a orthopaedic surgeon and meet the inclusion criteria can be included. Patients will be randomised between HTO en KJD (2:1). structural and clinical outcome parameters are evaluated over time up to 2 years.

Data on direct and indirect costs as well as change in quality of life are gathered by use of questionnaires.

Intervention

KJD is performed according to the methodology as used in previous knee distraction studies, using 2 monotubes, one laterally and one medially. Intra-operative the tubes are distracted 2 mm. During hospitalization the frame is further distracted, 1mm a day, until in total 5 mm is reached. Distraction lasts for 6 weeks whereby fully load bearing is encouraged, with crutches for stability. After 6 weeks the frame is removed at day-care surgery. HTO is performed as usual according to the clinical protocol.

Study burden and risks

All patients included will visit the outpatient clinic more frequently, namely a total of ten times in two years. At this visit questionnaires have to be filled in. Additionally 10 ml of blood and 5 ml of urine will be collected, an X-ray will be taken and 3 times a MRI examination will be performed, at baseline (KJD+HTO), 1yr (KJD) and 2yr (KJD+HTO) evaluation. Patients treated with KJD have the chance of developing pin-tract infections; this is a known complication of a *fixateur externe*. These skin infections can be effectively treated with antibiotics. Another possible disadvantage of KJD is that there is a higher risk for knee joint contracture, aimed to prevent by adequate physiotherapy. Rehabilitation will not be significantly different from HTO.

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

Patients with medial or lateral tibio-femoral compartmental OA considered for HTO according to regular clinical practice
Age < 65 years
Radiological joint damage: Kellgren & Lawrence score >2
Intact knee ligaments
Normal range-of-motion, normal stability
Maximum flexion limitation of 15 degrees (minimum of 120 degrees flexion pre-operative)
Body Mass Index < 35

Exclusion criteria

Mechanic axis-deviation of more than 10 degrees
Psychological inabilities or difficult to instruct
Not able to undergo MRI examination according to standard checklists
Inflammatory or rheumatoid arthritis present or in history
Post traumatic fibrosis due to fracture of the tibial plateau
Bone-to-bone contact in the joint (absence of any joint space on X-ray)
Surgical treatment of the involved knee < 6 months ago
Contra-lateral knee OA that needs treatment
Primary patello-femoral osteoarthritis

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Will not start

Enrollment:	69
Type:	Anticipated

Ethics review

Not approved

Date:	26-01-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL34302.041.10