Joint distraction as a treatment for end stage knee osteoarthritis: a comparison with presently applied surgical alternatives.

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1. Is KJD clinically non-inferior to current surgical techniques (HTO and TKP)?2. Is KJD superior to HTO in actual structural repair of cartilage?3. Is KJD cost-effective in the long-term compared to HTO and TKP?

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

Summary

ID

NL-OMON34828

Source
ToetsingOnline

Brief title
Knee Joint Distraction compared to osteotomy and total knee prosthesis

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

Intervention

Keyword: Cartilage repair, Distraction, Knee, Osteoarthritis

Outcome measures

Primary outcome

1. Clinical effectiveness determined by WOMAC.

Secondary outcome

2. Structural repair of cartilage as detemined on X-rays and MRI (only in

patients treated with KJD and HTO).

3. Costs -effectiveness measured using long-term (life-long) medical and

non-medical costs and Quality Adjusted Life Years as calculated, using the

health economic model

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) and total knee prosthesis (TKP) in two separate substudies. It is expected that KJD has equivalently or better clinical outcome.

Study objective

1. Is KJD clinically non-inferior to current surgical techniques (HTO and TKP)?
2. Is KJD superior to HTO in actual structural repair of cartilage?

3. Is KJD cost-effective in the long-term compared to HTO and TKP?

Study design

This study will be accomplished at the St. Maartenskliniek in Woerden (SMKW).
Ad 1) Two individual substudies (i.e. radomized controlled trials) are performed. One within patients considered for either HTO (cohort A) and one within patients considered for TKP (cohort B). Inclusion criteria are used so that all patients are also indicated to undergo KJD. In both cohorts patients are randomised to conventional treatment or KJD. Clinical outcome parameters are scored over 2 years and compared between treatment strategies within the two cohorts.
Ad 2) In cohort A (and patients undergoing KJD within cohort B) patients are also are evaluated for cartilage repair activity.
Ad 3) To calculate the model parameters as needed for the economic evaluation, a previously used and validated health-economic model for direct and indirect costs is used. This model is related to treatment and quality of life outcomes which will be measured in all cohorts. Furthermore, a third cohort of patients, undergoing knee-revision surgery (KReS, cohort C), is followed using the same measurements.

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, TKP and KReS are performed as usual according to the clinical protocol.

Study burden and risks

All patients included in cohort A or B will visit the outpatient clinic more frequently, namely seven times in two years. At this visit questionnaires have to be filled in, 10 ml of blood and 5 ml of urine will be collected and an X-ray will be taken.
For patients treated with KJD or HTO additionally 3 times a MRI examination will be performed, at baseline, 1yr and 2yr 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 or TKP.

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

Cohort A:
* Patients considered for HTO according to regular clinical practice
* Age < 65 years
* Radiological joint damage: Kellgren & Lawrence score > 2 (*2: mild but definite osteophyte formation, with essentially normal joint space width*)
* Normal range-of-motion, normal stability
* Maximum flexion limitation of 15 degrees (minimum of 120 degrees flexion pre-operative)
* Mechanic axis-deviation 5-10 degrees
* Non smoking

* Body Mass Index < 35;Cohort B:
* Patients considered for TKP according to regular clinical practice
* Age < 65 years
* Radiological joint damage: Kellgren & Lawrence score *2 (*2: mild but definite osteophyte formation, with essentially normal joint space width*)
* Intact knee ligaments
* Normal range-of-motion, normal stability
* Maximum flexion limitation of 15 degrees (minimum of 120 degrees flexion pre-operative)
* Non smoking
* Body Mass Index < 35;Cohort C:
* Patients considered for KReS according to regular clinical practice
* First revision of a TKP
* The original TKP placement under the inclusion criteria as defined for cohort B

Exclusion criteria

For cohorts A and B:
* Psychological inabilities or difficult to instruct
* Claustrofoby and therefore fear of MRI examination
* Inflammatory or rheumatoid arthritis present or in history
* Bone-to-bone contact in the joint (absence of a joint space on X-ray)
* Surgical treatment of the involved knee < 6 months ago
* Primary patello-femoral osteoarthritis;For cohorts C:
* Placement of the original TKP under the exclusion criteria as defined for cohort B.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	152
Type:	Anticipated

Ethics review

Not approved

Date:	15-09-2010
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	NL31659.041.10