Joint distraction in treatment of knee osteoarthritis: a comparison with a presently applied surgical alternative: total knee prosthesis

Published: 28-12-2010
Last updated: 04-05-2024

Primary:- To test the hypothesis that the clinical effect of KJD (determined by WOMAC) is not (clinically relevant) different from TKP at 2 years post treatment (equivalence hypothesis).
Secondary:- To describe and compare the clinical efficacy over…

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

Summary

ID

NL-OMON39144

Source
ToetsingOnline

Brief title
Knee joint distraction compared to total knee prosthesis

Condition

- 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. Clinical effectiveness determined by WOMAC.

Secondary outcome

2. Clinical effectiveness determined by KOOS.

3. Pain evaluated with VAS score.

4. Indication of costs-effectiveness.

5. Structural repair of cartilage as detemined on X-rays, MRI and biomarker

analysis (only in patients treated with KJD) in comparison with own baseline

values.

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 total knee prosthesis (TKP). It is expected that KJD has equivalent or better clinical outcome.

Study objective

Primary:
- To test the hypothesis that the clinical effect of KJD (determined by WOMAC)

is not (clinically relevant) different from TKP at 2 years post treatment (equivalence hypothesis).

Secondary:
- 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.
- The study will also be used to gather preliminary data on medical consumption and non-medical costs related to disease and treatment as well as quality of life.
- For the KJD group, tissue structure repair over 2 year follow-up compared to baseline will be evaluated, to increase the number of patients in a KJD cohort (ms added) in which structure modification has been evaluated. Extending this KJD cohort with data on structure modification provides a basis for future analyses on prediction of tissue structure repair after KJD.

Study design

This, multi-center, randomised controlled, non-blinded prospective 2 years follow-up trial will be accomplished at the Maartenskliniek Woerden (MK-W). Patients with severe OA of the knee, for whom conservative therapy fails and are indicated for a TKP by a orthopaedic surgeon and meet the inclusion criteria can be included. Patients will be randomised between TKP en KJD (2:1). 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.

Additionally, the KJD patients are monitored for tissue structure repair. Blood and urine will be collected before and up to 2 years after surgery. Samples are used for evaluation of biochemical markers of cartilage and bone synthesis and breakdown. Moreover, at baseline and over time up to 2 years, X-ray and MRI images are evaluated for cartilage and bone changes.

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. TKP is performed as usual according to the clinical protocol.

Study burden and risks

All patients included will visit the outpatient clinic more frequently, namely ten times in two years. At this visit questionnaires have to be filled in. For patients treated with KJD, 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, 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 TKP.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients considered for TKP according to regular clinical practice
Age < 65 years
Radiological joint damage: Kellgren & Lawrence score 2 or higher
Intact knee ligaments
Normal range-of-motion (min. of 120° flexion; max flexion limitation of 15°)
Normal stability
Body Mass Index < 35

Exclusion criteria

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
An infectious susceptible prosthesis (joint replacement) in situ
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:	Recruitment stopped
Start date (anticipated):	09-03-2011

Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	28-12-2010
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-04-2011
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-03-2014
Application type:	Amendment
Review commission:	METC NedMec

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	NL34296.041.10