Joint distraction in treatment of knee osteoarthritis; long-term radiographic evaluation of structural joint changes

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To analyse long-term structural joint changes after knee joint distraction as a treatment for knee osteoarthritis by use of radiographs

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON45795

Source
ToetsingOnline

Brief title
Long-term structural joint changes after Knee Joint Distraction

Condition

- Joint disorders

Synonym
arthrosis, knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Stichting Vrienden UMC Utrecht

Intervention

Keyword: Knee Joint Distraction, osteoarthritis

Outcome measures

Primary outcome

Joint space narrowing as measured on radiographs

Secondary outcome

Subchondral sclerosis as measured on radiographs.

Osteophyte size as measured on radiographs

Study description

Background summary

For patients with severe knee osteoarthritis (OA), knee joint distraction (KJD) has been proven to be clinically beneficial and cartilage tissue repair has been demonstrated. The longest follow-up thus far has followed 20 KJD patients from an open, uncontrolled prospective study (METC protocol 04/086) for up to 9 years, where 8 of these patients were still available for radiographic and clinical questionnaire evaluation. Another 42 patients were treated with KJD in two randomized controlled trials (RCTs) comparing KJD with the current conventional treatments of total knee arthroplasty (METC protocol 10/359/E, 20 KJD patients treated) and high tibial osteotomy (METC protocol 11/072, 22 KJD patients treated). In all patients, radiographic and clinical questionnaire evaluation was performed up to two years. At this moment, 4 to 7 years after treatment, 26 of the KJD patients (10 from the arthroplasty trial, 16 from the osteotomy trial) are still followed up clinically with yearly questionnaires. However, no radiographs have been made after two years. Since the beneficial long-term clinical and radiographic results of the prospective study could be measured only in a very small number of patients, we are interested to evaluate the long-term radiographic changes in this larger group of KJD patients and how these changes relate to their clinical follow-up. To better understand joint changes over time, we willperform radiographs as soon as possible (which, considering the current follow-up times, would be at 6 ± 2 years) and at the last moment of follow-up (10 years).

Study objective

To analyse long-term structural joint changes after knee joint distraction as a treatment for knee osteoarthritis by use of radiographs

Study design

An observational study with one radiograph performed at two separate follow-up moments.

Study burden and risks

The patients are already contacted yearly by a researcher for the questionnaires and will now be called and asked if they would be willing to participate in this additional research. After two weeks they will be called again. If they are still interested in participation, they will be asked to come to the UMCU for an appointment with the researcher, where they will be asked to sign informed consent. In the same visit they will have the first radiograph taken. When they reach 10 years of follow-up after KJD, they are asked to come to the UMCU for one more radiograph.

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

Participation in one of both RCTs: Knee Joint Distraction vs. High Tibial Osteotomy or Knee Joint Distraction vs. Total Knee Prosthesis (METC protocol 10/359/E and 11/072) and randomised to KJD treatment.
Still participating in long-term follow-up of these trials.

Exclusion criteria

Patients are excluded if they received additional surgery in their KJD-treated knee after the last filled-in questionnaire they sent us (in which they indicated they had not received additional surgery until that moment).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2019
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2019
Application type:	First submission
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	NL67845.041.18