Joint distraction in the treatment of severe knee osteoarthritis; optimizing the method.

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

Summary

ID

NL-OMON33996

Source
ToetsingOnline

Brief title
Joint distraction in the treatment of severe knee osteoarthritis

Condition

- Joint disorders

Synonym
arthrosis, 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 regeneration, joint distraction, knee osteoarthritis

Outcome measures

Primary outcome

The primary outcome parameter will be clinical effectivity determined by the WOMAC questionair on pain, function and stiffness. Structural effectivity will be analysed on x-ray and MR. The treatment with one month distraction is considered effective if three out of four patients have comparable results with the previous study of two months distraction.

Secondary outcome

A secundary outcome parameter is clinical effectivity based on physical examination. There will also be a more specific analysis on biological change of the joint by biomarker and MR analysis.

Pin tract infections will be registered and retrospectively compared to the two month distraction study.

Study description

Background summary

Knee osteoarthritis is a degenerative joint disorder affecting a large part of our population (10%). Current treatment aims at diminishing symptoms instead of curing the disease.
Joint distraction in ankle osteoarthritis has proven its effectivity; twothirds of patients have good results for at least ten years. Actual joint regeneration, 'cure', is suggested on x-ray. Preliminary results in studying knee distraction are also very promising, pain decreases and again joint regeneration is suggested on MR and x-ray.
The current method for the knee joint consists of two months distraction with a external fixator, which is a very invasive treatment, especially for the

patient but also for our health system. Pin tract infection is a very common and painfull complication. Also, the two month fixation of the knee joint effects muscle condition and knee flexion range, resulting in a long revalidation period.

Study objective

The minimal duration of an effective distraction period has not yet been determined. In the past, two months distraction showed comparable results with three month distraction. In this study, we would like to analyse the effectivity of a one month distraction period on severe knee osteoarthritis. Considering the burden of the distraction period for patient as well as for the health system, a reduction of this period would make this promising treament more suitable for broader implementation.

Study design

In this pilot study four patients will be treated with one month joint distraction. These patients will be followed for one year.

Intervention

Patients will be treated with an external fixator bridging the knee joint. Two monotubes are placed on bone pines, four pins in the femur and four in the tibia. The joint is distracted for at least five millimeter during the first few days. Every week, patients come back to the outpatient clinic to see if distraction is still present and check for pin tract infections. After one month the distraction frame is removed under general anesthesia and the knee joint is flexed. The patient will be followed for one year.

Study burden and risks

Joint distraction is an invasive treatment with a significant risk on complications. The main complication is pin tract infection, as occurs with all external fixators, which can be treated effectively with antibiotics and pain medication.
This specific group of young knee osteoarthritis patients has no other treatment options. Thusfar, results of joint distraction are very promising. Our purpose in this study is to combine the promising effectiveness of this treatment with a more acceptable treatment method for the patient.

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

Age < 60 yrs
Primarily tibia-femoral osteoarthritis
Clinical indication for arthroplasty or osteotomy
Radiographic knee OA; K&L > 2

Exclusion criteria

Bilateral knee osteoarthritis
Joint malalignment > 10°
History of infectious arthritis
Primarily patello-femoral osteoarthitis
Knee instability with physical examination
Psychological difficulties which interfer with joint distraction

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	4
Type:	Anticipated

Ethics review

Not approved

Date:	17-03-2009
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	NL25701.041.09