Feasibility of personalised hinged knee distraction

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Feasibility of knee motion reproduction method for application in a hinged knee distraction device to apply reliable comfortable hinged knee joint distraction to be tested in future clinical studies.

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

Summary

ID

NL-OMON41723

Source
ToetsingOnline

Brief title
Feasibility of personalized hinged knee distraction

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: joint distraction, knee, osteoarthritis

Outcome measures

Primary outcome

Joint space width on standardised X-rays evaluated by knee image digital analyses (KIDA; Marijnissen A, et al, O&C 2008).

Reliable hinged knee joint distraction: viz. enlarged (>3 mm as compared to no distraction) joint space width under X-ray vision under extension and flexion (0-30 degrees) during weight bearing; with smooth joint movement (0-30 degrees flexion; arbitrary to the patients satisfaction, and orthopaedic surgery*s judgement) during flexion/ extension.

Secondary outcome

Optimal process characteristics including motion capture, manufacturing of patient specific part, and distraction application. These parameters are arbitrary and relate to feasibility, logistics, time, etc. Only based on the first experience in the proposed feasibility study exact endpoints can be set with input of all stakeholders for future treatment studies.

Study description

Background summary

Knee joint distraction with a conventional (viz. stiff) joint distraction device in treatment of severe knee osteoarthritis (OA) has shown significant prolonged clinical benefit compared to pre-treatment conditions (decreased pain and increased function). At present knee joint distraction becomes implemented in clinical practice.
During conventional distraction, flexion (motion) of the knee joints is not

possible for 6-8 weeks. This is despite good and prolonged clinical benefit, a significant discomfort for patients during the distraction period.
We developed, mechanically tested, and patented a (personalised) hinged knee joint distractor. This new hinged distractor uses exactly the same bilateral fixation technique as the conventional stiff distractor. However, hinges are used to bridge the joint which have a patient-specific part inside that accurately reproduces the patient-specific joint motion. To capture the patient*s specific movement, a non-invasive digital measurement tool has been developed as accessory to the hinged distractor. Dedicated software generates data for automated manufacturing of the patient-specific parts of the hinged knee distractor. These are manufactured directly and are placed in the hinged distraction device.
Feasibility and proof of correct of the process of motion reproduction and manufacturing of the patient specific parts as well as the actual hinged distraction is required before the technique of hinged knee distraction can actually be applied in an experimental treatment (feasibility/safety) study.

Study objective

Feasibility of knee motion reproduction method for application in a hinged knee distraction device to apply reliable comfortable hinged knee joint distraction to be tested in future clinical studies.

Study design

Observational, technical feasibility study, with invasive (X-ray) measurements without follow-up.

Study burden and risks

Patients will visit during conventional (stiff) distraction the outpatient clinic on a regular basis. At one of these visits a day-care visit for the present study is scheduled. The hinged distractor is fixed to the same bone pins in place for conventional distraction. There is no direct benefit for the patients in this study. The burden is significant during this specific one day study visit. The risks are limited. In the first knee joint distraction studies (METC 01-146 and 04-086) conventional distraction tubes were every two weeks removed during day-care and patients knee flexion was exercised for several hours on a continuous passive motion device. This was done over a 2-3 months period (3-5 times). Every time distraction was regained and checked by X-ray. Based on this experience the risk of removing and reinstalling conventional distraction is considered limited. The extra 7 radiographs is an acceptable risk and not uncommon in regular practice for diagnosis and follow-up of knee osteoarthritis.

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

25BMI < 35
Normal-good physical condition (arbitrarily defined by orthopedic surgeons)
Normal knee joint stability
Normal range of motion (including full extension)
Radiographic signs of joint damage (KL grade 2-3)

Exclusion criteria

- Comorbidities that could interfere with the study (arbitrary defined by orthopaedic surgeons)
- History of inflammatory or septic arthritis

- Knee mal-alignment of more than 5 degrees
- Previous severe ligament damage (including reconstructions)
- Previous intra-articular fractures
- Laser treatment of cartilage
- Previous surgical interventions of the distracted knee < 6 months ago
- Absence of any joint space width on either site (medial or lateral) of X-ray

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2015
Enrollment:	4
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-10-2015
Application type:	Amendment
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	NL48424.041.14