'User-friendly' knee distraction for treatment of osteoarthritis compared to conventional 'proof-of-concept' knee distraction treatment

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

Summary

ID

NL-OMON43216

Source
ToetsingOnline

Brief title
User-friendly knee distraction

Condition

- Joint disorders

Synonym
knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ZonMw,Vrienden UMC Utrecht

Intervention

Keyword: distraction, knee, osteoarthritis, user-friendliness

Outcome measures

Primary outcome

A: surgery time needed to place the knee joint distractor

B: clinical efficacy by KOOS/WOMAC questionaire based on pain, function and

stifness after 2 years

Secondary outcome

A: convienence/burden of wearing the device for 6-7 weeks of the knee

distractor (questionnaire)

B: joint space width (cartilage thickness) on radiographs after 2 years

Study description

Background summary

Severe knee osteoarthritis below the age of 65 years can effectively be treated with 'knee joint distraction' being a joint saving surgery.
The UMC Utrecht has gathered ample evidence that knee joint distraction using a 'proof-of-concept' (experimental) knee joint distractor is very (cost)effective. Recently the UMC Utrecht has developed a CE certified 'user friendly' knee distractor with similar mechanical properties and making use of the same bone pin locations, but more easy (quicker) to install for the orthopaedic surgeon and more easy (less burdensome) to wear for the patient.

Study objective

The present study aims at a small randomised study demonstrating user friendliness of the 'user friendly' knee joint distractor compared to the experimental 'proof of concept' device (2*15 patiënten). Additionally the study aims in a large patient group (n=+60) to confirm clinical efficacy of the novel 'user friendly' knee joint distractor by demonstrating non-inferiority compared

to retrospective data obtained from clinical studies with the 'proof-of-concept' device.

Study design

A: user friendliness: multi centre open randomised study
B: efficacy: multi centre open observational study with retrospective comparison

Intervention

'user friendly' knee joint distraction (vs. 'proof-of-concept' knee distraction)

Study burden and risks

- limited unexpected risk of failure of the new 'user friendly'knee joint distractor
- limited extra time needed to fill in questionnaires
- minimal risk because of increased radiation exposure due to two extra knee x-rays

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

Patients with severe knee osteoarthritis (persisting conventional treatment resistant pain and cartilage tissue damage) considered for total (or uni) knee arthroplasty or high tibial osteotomy (with limited axis deviation), in general practice by the orthopaedic surgeon offered knee joint distraction as alternative treatment.
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- adults *65 years of age (at higher ages cost-benefit is becoming less; 15)
- BMI < 35 kg/m2 (mechanical safety limit of device) (max 110 kg body weight)
- Normal-good physical condition (arbitrary defined by orthopaedic surgeons)
- Sufficient knee joint stability (arbitrary defined by orthopaedic surgeons)
- Sufficient range of motion (arbitrary defined by orthopaedic surgeons)
- Radiographic signs of joint damage (KL grade 2-4)
- VAS (visual analogue scale) pain >40/100 (conservative treatment resistant)

Exclusion criteria

General: Patients that would not be considered for arthroplasty or osteotomy because of psychosocial condition (e.g. pain syndroms); or who meet any of the following criteria will be excluded from participation in this study:
- Comorbidities that would compromise the efficacy of knee joint distraction (arbitrary defined by orthopaedic surgeons)
- History of inflammatory or septic arthritis
- Knee mal-alignment of more than 10 degrees
- Previous surgical interventions of the index knee < 6 months ago
- Absence of any joint space width on both sides (medial and lateral) of X-ray
- presence of an endo-prostheses elsewhere

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	90
Type:	Anticipated

Medical products/devices used

Generic name:	knee distractor
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	01-12-2016
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	NL57631.041.16