User-friendliness of *ArthroSave*s Knee-Reviver* compared to *Stryker mono-tubes* in case of knee distraction as treatment for knee osteoarthritis.

Published: 12-07-2017
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Goals is Doel to study whether this new distractor is indeed more userfriendly.

Ethical review	Not approved
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON45556

Source
ToetsingOnline

Brief title
User-friendly knee-distraction

Condition

- Bone and joint therapeutic procedures

Synonym
knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw,Vrienden UMCU

Intervention

Keyword: distraction, knee, osteoarthritis

Outcome measures

Primary outcome

duration needed to place the distraction frame

Secondary outcome

questionnaire regarding user friendliness for the patient

Study description

Background summary

Total knee prostheses are placed in case no treatment options are available anymore 10.000/year in patients below the age of 65 years
Knee distraction is a joint saving treatment for these relatively young patients and can postpone a first total knee prosthesis and with that can prevent the change for revision surgery later in life.
The presently available knee distractor is a proof-of-concept device and not suitable for broad implementation in clinical practice.
The UMC Utrecht has developed a user friendly knee distractor together with ArthroSave BV (ArthroSave's KneeReviver) specifically designed for knee distraction as treatment for osteoarthritis, enabling broad implementation in clinical practice.

Study objective

Goals is Doel to study whether this new distractor is indeed more userfriendly.

Study design

randomized 3-center study comparing user-friendliness of the proof-of-concept distractor with ArthroSave's KneeReviver

Intervention

knee distraction with ArthroSave's KneeReviver

Study burden and risks

Burden is not different (potentially less) than regular distraction treatment. Only 2 short questionnaires are filled in. ArthroSave*s Knee-Reviver has never been tested on humans in clinical practice. This provides a potential risk of unforeseen complications. The change is very small. In that case a conventional distractor can be placed. With this proven effective distractor treatment can be continued.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- adults *65 years of age (at higher ages cost-benefit is becoming less; 15)

- BMI < 35 kg/m2 (mechanical safety limit of device) (with 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; 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:	30
Type:	Anticipated

Medical products/devices used

Generic name:	ArthroSave's Knee-reviver
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	12-07-2017
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	NL60309.041.17