Prospective follow-up of clinical efficacy of knee distraction as treatment for knee OA by use of 'ArthroSave's Knee-Reviver'.

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To document clinical efficacy of ArthroSave*s Knee-Reviver at 1, 2 and 5 years after distraction by:1st: an increase in WOMAC score (pre-treatment vs. follow-up).2nd: an increase in radiographic joint space width (pre-treatment vs. follow-up)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON55548

Source
ToetsingOnline

Brief title
Prospective follow-up of 'ArthroSave's Knee-Reviver'.

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

WOMAC score (pre-treatment vs. follow-up)

radiographic joint space width (pre-treatment vs. follow-up)

Secondary outcome

To document changes in general well-being after Knee Joint Distraction, using

ArthroSave*s Knee-Reviver (using SF-36 questionnaire)

To document clinical efficacy/ patient satisfaction of subsequent surgical

procedures after KJD

Study description

Background summary

Knee joint distraction is a surgical technique by which the two bony ends of the knee joint are separated for a few mm for a few weeks by use of an external distraction device. This (by the UMC Utrecht developed) treatment for severe end stage knee osteoarthritis below the age of 65 years is clinically very effective and results in joint tissue repair. Most importantly this treatment can postpone the initially indicated total knee prosthesis (knee arthroplasty) for over 5 years up to even 10 years in * of the treated patients. With that this joint saving treatment can prevent the need for costly and less effective prosthesis revision surgery. This makes this novel joint distraction treatment very cost effective. However, thus far all studies have been performed with a *proof-of-concept* (off-the-shelf) medical device designed for trauma surgery (Stryker monotubes). Despite the clinical benefit, these monotubes are unnecessary burdensome for patients to wear (unnecessary bulky) during the 6 weeks distraction period. Moreover, with these Stryker tubes the surgical procedure is unnecessary complex and time consuming (too many bolt and nuts to tighten, limited flexibility in positioning). This results in unnecessary inconvenience for patients and surgeons. The UMC Utrecht has therefore developed in collaboration with ArthroSave a *user-friendly* dedicated knee

joint distraction device called *the Knee-Reviver*. This device has the similar essential mechanical properties (as part of the requirements of its CE marking) and makes use of the same pin fixation positions as the Stryker tubes. As such clinical outcome of treatment is considered to be equal to that of the Stryker device. But clinical efficacy of ArthroSave*s Knee-Reviver has never been evaluated.

Study objective

To document clinical efficacy of ArthroSave*s Knee-Reviver at 1, 2 and 5 years after distraction by:
1st: an increase in WOMAC score (pre-treatment vs. follow-up).
2nd: an increase in radiographic joint space width (pre-treatment vs. follow-up)

Study design

Prospective uncontrolled 5 centre, 5 years follow-up study; n=75 patients, 15 patients per institute.

Study burden and risks

Knee joint distraction for the designated population is at present by the UMC Utrecht, Maartens Kliniek, and Maastricht UMC performed in clinical practice using the Stryker mono-tubes. Over 100 patients have been treated without adverse events due to the mechanical properties of the device. Knee joint distraction using ArthroSave*s Knee-Reviver has no additional risk as compared to distraction treatment with the Stryker monotubes as this anticipated user-friendly knee distractor uses the same bone pin positions, and has the same mechanical characteristics (all part of the CE certification) providing mechanically an essential similar treatment. As such similar clinical benefit is anticipated. However, ArthroSave*s Knee-Reviver (although CE certified with knee joint distraction for osteoarthritis as intended use) has never been tested on humans in clinical practice. This provides a potential risk of unforeseen, though unanticipated, complications.

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

- 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: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2017
Enrollment:	70
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	03-07-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-02-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-01-2019

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-03-2021
Application type:	Amendment
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	NL60730.041.17