Prospective follow-up of clinical efficacy of knee distraction as treatment for knee osteoarthritis by use of ‘ArthroSave’s Knee-Reviver’

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Joint distraction using the userfriendly KneeReviver is clinically effective in the treatment of severe knee osteoarthritis, based on an increase in WOMAC score and an increase in joint space width.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25021

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Knee osteoarthritis

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: ZonMW, Vrienden van UMC Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

WOMAC score and radiographic joint space width evaluated by KIDA software

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 (see figure in introduction). 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 ¾ 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.

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 population: Patients with severe knee osteoarthritis (with persisting, conventional treatment resistant pain with cartilage tissue damage) considered for total (or compartmental) knee arthroplasty or high tibial osteotomy (with limited axis deviation), below the age of 65 years, and in general practice by the orthopaedic surgeon offered knee joint distraction as alternative treatment.

Intervention (if applicable): knee joint distraction as performed in regular clinical practice using ArthroSave’s Knee-Reviver (CE marked with indication for knee distraction treatment in case of knee osteoarthritis).

Main study parameters/endpoints: Clinical efficacy by use of an increase in WOMAC score and an increase in joint space width.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Doel van het onderzoek

Joint distraction using the userfriendly KneeReviver is clinically effective in the treatment of severe knee osteoarthritis, based on an increase in WOMAC score and an increase in joint space width.

Onderzoeksopzet

0,1,2,5 years

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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) (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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2017
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	30-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7986
Ander register	METC UMC Utrecht : METC #17-293

Resultaten