Knee Joint Distraction in comparison with Total Knee Prosthesis in treatment of knee osteoarthritis.

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The clinical effect of Knee Joint Distraction (determined by WOMAC) is not (clinically relevant) different from Total Knee Prosthesis at two years post treatment (equivalence hypothesis).

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26791

Bron
NTR

Aandoening

Osteoarthritis of the knee.

Ondersteuning

Primaire sponsor: Universital Medical Center Utrecht
Overige ondersteuning: ZonMW
Universital Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Clinical effectiveness determined by WOMAC at two years.

Toelichting onderzoek

Achtergrond van het onderzoek

This, multi-center, randomised controlled, non-blinded prospective 2 years follow-up trial will be accomplished at the Maartenskliniek Woerden (MK-W) in collaboration with the University Medical Center Utrecht (UMCU). Patients with severe OA of the knee, whom are indicated for a TKP by a orthopaedic surgeon and meet the inclusion criteria are asked to participate. When included, patients will be randomised between TKP en KJD (2:1). Clinical outcome parameters are evaluated over time up to 2 years. Data on direct and indirect costs as well as change in quality of life are gathered by use of questionnaires. Additionally, the KJD patients are monitored for tissue structure repair. Blood and urine will be collected before and up to 2 years after surgery. Samples are used for evaluation of biochemical markers of cartilage and bone synthesis and breakdown. Moreover, at baseline and over time up to 2 years, X-ray and MRI images are evaluated for cartilage and bone changes.

Doel van het onderzoek

The clinical effect of Knee Joint Distraction (determined by WOMAC) is not (clinically relevant) different from Total Knee Prosthesis at two years post treatment (equivalence hypothesis).

Onderzoeksopzet

Baseline (2x), 3 and 6 weeks, 3, 6, 9, 12, 18 and 24 months follow-up.

Onderzoeksproduct en/of interventie

KJD is performed according to the methodology as used in previous knee distraction studies, using 2 monotubes, one laterally and one medially. Intra-operative the tubes are distracted 2 mm. During hospitalization the frame is further distracted, 1mm a day, until in total 5 mm is reached. Distraction lasts for 6 weeks whereby fully load bearing is encouraged, with crutches for stability. After 6 weeks the frame is removed at day-care surgery.

TKP is performed as usual according to the clinical protocol.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients considered for TKP according to regular clinical practice;

2. Age < 65 years;

3. Radiological joint damage: Kellgren & Lawrence score above 2;

4. Intact knee ligaments;

5. Normal range-of-motion (min. of 120° flexion; max flexion limitation of 15°);

6. Normal stability;

7. Body Mass Index < 35.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Psychological inabilities or difficult to instruct;

2. Not able to undergo MRI examination (standard protocol);

3. Inflammatory or rheumatoid arthritis present or in history;

4. Post traumatic fibrosis due to fracture of the tibial plateau;

5. Bone-to-bone contact in the joint (absence of any joint space on X-ray);

6. Surgical treatment of the involved knee < 6 months ago;

7. An infectious susceptible prosthesis (joint replacement) in situ;

8. Primary patello-femoral OA.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2011
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-03-2011
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	NL2680
NTR-old	NTR2809
Ander register	METC UMCU : 10-359
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A