Knee Joint Distraction in comparison with High Tibial Osteotomy in treatment of knee osteoarthritis.

Gepubliceerd: 16-05-2011 Laatst bijgewerkt: 18-08-2022

Denuded bone areas are filled up with cartilage (determined with quantitative MRI) which is not anticipated to occur in case of HTO. The cartilage changes are compared two years post treatment.

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

Samenvatting

ID

NL-OMON25422

Bron
NTR

Aandoening

Osteoarthritis, Knee

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: University Medical Center Utrecht (UMCU), ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cartilage changes determined by decrease in denuded bone areas using quantitative MRI analyses.

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 high tibial osteotomy by a orthopaedic surgeon and meet the inclusion criteria are asked to participate. When included, patients will be randomised between High Tibial Osteotomy and Knee Joint Distraction (2:1). All patients will be monitored for tissue structure changes which will be evaluated over time up to two years. Quantitative MRI images and X-rays are analyzed for cartilage changes. 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, clinical outcome parameters and data on direct and indirect costs as well as change in quality of life are gathered by use of questionnaires.

Doel van het onderzoek

Denuded bone areas are filled up with cartilage (determined with quantitative MRI) which is not anticipated to occur in case of HTO. The cartilage changes are compared two years post treatment.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Knee Joint Distraction 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 2mm. During hospitalisation the frame is further distracted, 1mm a day, until in total 5mm 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.

High Tibial Osteotomy is performed as usual according to the clinical protocol.

Contactpersonen

Publiek

Heidelberglaan 100

K. Wiegant
Utrecht
The Netherlands
+31 (0)88 7559428

Wetenschappelijk

Heidelberglaan 100
K. Wiegant
Utrecht
The Netherlands
+31 (0)88 7559428

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with medial or lateral tibio-femoral compartmental OA considered for HTO 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);

6. Normal stability;

7. Body Mass Index < 35.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mechanic axis-deviation (varus-valgus) of less than 10 degrees;

2. Psychological inabilities or difficult to instruct;

3. Not able to undergo MRI examination (standard daily clinical practice protocol);

4. Inflammatory or rheumatoid arthritis present or in history;

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

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

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

8. Contra-lateral knee OA that needs treatment;

9. 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:	01-05-2011
Aantal proefpersonen:	69
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-05-2011
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	NL2761
NTR-old	NTR2900
Ander register	METC UMCU : 11-072/E
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A