Joint distraction in the treatment of knee osteoarthritis: efficacy and underlying mechanisms.

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A two month distraction period results in similar clinical beneficial effects as a three month distraction period.

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

Samenvatting

ID

NL-OMON20489

Bron
Nationaal Trial Register

Verkorte titel
Joint distraction in the treatment of knee osteoarthritis: efficacy and underlying mechanisms.

Aandoening

Osteoarthritis of the knee is a progressing degenerative joint disorder, characterised by joint pain and limitation of movement, leading to disability. Tissue changes comprise damage of joint cartilage, synovial inflammation and changes in subchondral bone, such as subchondral sclerosis and osteophyte formation (bony outgrowths).

Ondersteuning

Primaire sponsor: University Medical Center Utrecht,
Rheumatology & Clin. Immunology and Orthopaedics
Overige ondersteuning: Dutch Arthritis Association, RVVZ

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pain (according to the WOMAC).

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction:

Joint distraction is a relatively new approach in the treatment of severe osteoarthritis (OA). Clinical efficacy has been proven for hip and ankle OA.

Methods:

Patients with severe posttraumatic OA of the tibio-femoral joint, who were considered for an endoprosthesis were treated with joint distraction. Two external fixation tubes, bridging the knee joint, were placed on pins that were drilled through soft tissue and bone. Joint distraction was performed gradually until 5mm was reached (radiographically controlled). To avoid contractures of the knee joint, each two weeks the distraction tubes were removed from the pins to exercise the joint without loading. After exercising, the distraction of the joint was replaced and controlled radiographically. Absence of mechanical load on the cartilage, preventing further wear and tear, was controlled on standardized radiographs. Pain, functional disability, clinical condition, and flexion of the joint were evaluated using a box-scale, a questionnaire (slightly modified WOMAC) and by physical examination.

Doel van het onderzoek

A two month distraction period results in similar clinical beneficial effects as a three month distraction period.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Joint distraction applies temporary (2 months) relief of mechanical wear and tear of the articular cartilage surfaces forming a joint. Nutrition of the cartilage is maintained due to

intra-articular fluid pressure changes during treatment. Additionally subchondral sclerosis is diminished, diminishing mechanical stresses on the cartilage after treatment.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age < 55 years;

2. Osteoarthritis, primary in the tibio-femoral joint, uni or bilateral;

3. Severe osteoarthritis considered for joint replacement surgery/osteotomy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Osteoarthritis in both knees;

2. Primary retro-patellar osteoarthritis;

3. Deviation of the mechanical axis >10 º (independent of cartilage damage);

4. Primary intra-articular inflammation;

5. Psychological problems, not allowing 2 months distraction.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-07-2004
Aantal proefpersonen:	3
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-08-2005
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	NL419
NTR-old	NTR459
Ander register	: N/A
ISRCTN	ISRCTN92846059

Resultaten

Samenvatting resultaten
N/A