Comparing two different designs of total knee arthroplasty in 120 patients: 60 patients receive the prosthesis in which the posterior cruciate ligament is spared and 60 patients receive the prosthesis in which the ligament is sacrificed.

Gepubliceerd: 19-02-2009 Laatst bijgewerkt: 18-08-2022

The patients’ perceived outcome scores higher in the group with the posterior stabilized total knee arthroplasty.

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

Samenvatting

ID

NL-OMON24528

Bron
NTR

Verkorte titel
AGC trial

Aandoening

osteoarthritis, total knee arthroplasty, posterior cruciate ligament, posterior stabilized

Ondersteuning

Primaire sponsor: Martini Hospital Groningen, University Medical Centre Groningen, the Netherlands
Overige ondersteuning: Martini Hospital Groningen, University Medical Centre Groningen, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To examine whether there is a difference in patients perceived outcome between a posterior cruciate retaining total knee arthroplasty compared with a posterior stabilized total knee arthroplasty.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Prosthetic design for use in the primary knee arthroplasty has evolved into those designs that preserve the posterior cruciate ligament (PCL) and those in wich the ligament is routinely sacrificed (posterior stabilized). Cruciate-retaining designs have a posterior cutout for the posterior cruciate ligament and relatively flat topography, allowing for posterior roll-back of the femur when the knee is flexed and the posterior cruciate ligament is tensioned.
Posterior stabilized implants in wich the ligament is excised may substitute for this function by an intercondylar tibial prominence that articulates with the femur in flexion, aiding in femoral roll-back..It is not known whether there is any difference in patients' perceived outcome between a posterior cruciate retaining total knee arthroplasty compared with a posterior stabilized total knee arthroplasty.

Objective:

Primary objective is to examine whether there is a difference in patients' perceived outcome between a posterior cruciate retaining total knee arthroplasty compared with a posterior stabilized total knee arthroplasty.

Study design:
double blinded, randomized controlled clinical trial.

Study population:
patients with primary symptomatic osteoarthrosis of the knee and applying the inclusion criteria.

Intervention (if applicable):
60 patients receiving the posterior stabilized total knee arthroplasty, 60 patients receiving the posterior cruciate ligament retaining total knee arthroplasty.

Main study parameters/endpoints:
Primary outcome parameter:
WOMAC score.

Secondary outcome parameters:
range of motion, quality of life, gait parameters, femoral roll back (=relative internal tibial rotation with flexion of the knee as the lateral condyle moves more posteriorly due to less constraint).

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

Besides the existing risks after placing a total knee arthroplasty no extra risks are being expected. The current follow up moments for total knee arthroplasty at the outpatient clinic are being used, and merely some questionnaires are taken which takes only a few minutes extra per patient.
Also there is a pre- and postoperative gait-analysis at the department of physical therapy, where the patient is already training under supervision of a therapist like in the current protocols, so this is expected to be hardly a burden to the patient.

The study design and procedures are approved by the local Medical Ethical Committee (2007-23). The study will be conducted at the Department of Orthopaedic Surgery of the Martini Hospital, which is a large teaching hospital in the city of Groningen, the Netherlands. Participation in the study is voluntary and informed consent is required.

Doel van het onderzoek

The patients’ perceived outcome scores higher in the group with the posterior stabilized total knee arthroplasty.

Onderzoeksopzet

Measurements will take place preoperatively, 6 weeks, 3 months, 6 months and 1 year postoperatively.

Onderzoeksproduct en/of interventie

60 patients receive the posterior stabilized total knee arthroplasty, 60 patients receive the posterior cruciate ligament retaining total knee arthroplasty.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Primary symptomatic osteoarthritis of the knee;

2. Non fixed varus and valgus deformity of less than 10 degrees;

3. Age between 55 and 85 years;

4. BMI less than 35 kg/m2;

5. ASA I and II.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Secondary osteoarthrosis of the knee;

2. (Active) arthritis (eg rheumatic disease);

3. Flexion less than 90 degrees;

4. Flexion contracture over 10 degrees;

5. Peripheral neuropathy;

6. History of CVA;

7. Previous osteotomy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-02-2009
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	NL1593
NTR-old	NTR1673
Ander register	METC Groningen : 2007-23
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A