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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24528

Source
NTR

Brief title
AGC trial

Health condition

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

Sponsors and support

Primary sponsor: Martini Hospital Groningen, University Medical Centre Groningen, the Netherlands
Source(s) of monetary or material Support: Martini Hospital Groningen, University Medical Centre Groningen, the Netherlands

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To determine whether there is a difference in range of motion between a posterior cruciate retaining total knee arthroplasty compared with a posterior stabilized total knee arthroplasty. Additionally, to determine whether there is a difference in Knee Score (physician-based outcome score), health-related quality of life, gait parameters and femoral roll back.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-02-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1593
NTR-old	NTR1673
Other	METC Groningen : 2007-23
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A