Retention of the posterior cruciate ligament versus the posterior stabilized design in total knee arthroplasty: a prospective randomized controlled clinical trial

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON30597

Source
ToetsingOnline

Brief title
Retention versus sacrifice of the PCL in total knee arthroplasty.

Condition

- Joint disorders

Synonym
osteoarthrosis of the knee joint

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: posterior cruciate ligament, posterior stabilized, total knee arthroplasty

Outcome measures

Primary outcome

Patients perceived outcome after TKA as determined with the WOMAC

questionnaire.

Secondary outcome

Range of motion

Knee Society Clinical Rating System as physician-based outcome score after TKA.

Quality of Life as determined with the Short Form 36 (SF-36)

Gait parameters

Femoral roll back

Study description

Background summary

Prosthetic design for use in the primary knee arthroplasty has evolved into those designs that preserve the posterior cruciate ligament and those in wich the ligament is routinely sacrificed (posterior stabilized).
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.
In the current practice both designs are used. In patients which a non functional PCL the posterior stabilised design is used. However, in patients with a functional PCL the decision which design is chosen depends largely on the favor and training of the surgeon. A limited amount of studies have been performed into the difference in outcome of the two designs. These studies are

characterised by a small amount of patients, different outcome measures, poor randomisation and comparing designs of different manufacturers. Range of motion was the only common outcome parameter; a meta-analysis showed a difference in range of motion and reproduction angle favoring posterior stabilized designs over PCL retention designs one year postoperatively. However, it is uncertain whether this observation is of clinical relevance2. There have been no studies performed yet determining if there is a difference between designs in patients* perceived outcome. Additionally, there is a lack of studies determining the speed of recovery in both designs as most studies only determine the final outcome (eg after one year).

Study objective

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

Randomized controlled clinical trial.
Patients that are scheduled for a primary total knee arthroplasty and apply to the inclusion criteria of the study are informed about the trial. After consent to participate, patients are randomised in two groups. As two surgeons (R.W. Brouwer and J.J.A.M. van Raay) will perform the surgical procedure, block randomisation is used. In total 120 patients will be randomised, 60 patients in each group (60 patients per surgeon).
Measurements will take place preoperatively, 6 weeks, 3 months, 6 months and 1 year postoperatively.
The study will be double blinded: Clinical examination will be performed by a blinded independent person and the patient will not be informed about which design is used during the length of the study.
The study will be executed in the Martini Hospital Groningen. Duration of the study will be 2 years, starting from August 2007.

Intervention

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

Study burden and risks

Besides the existing risks after placing a total knee arthroplasty no extra risks are being expected.
The current follow up moments 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

primary symptomatic osteoarthrosis of the knee
non fixed varus and valgus deformity of less than 10 degrees
age between 55 and 85 years
BMI less than 35 kg/m2
ASA I and II

Exclusion criteria

secondary osteoarthrosis of the knee
(active) arthritis (eg rheumatic disease)
flexion less than 90 degrees
flexion contracture over 10 degrees
peripheral neuropathy
history of CVA

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2008
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	22-08-2007
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL16071.056.07