Freedom through constraint? A randomized clinical trial on posterior stabilization in mobile bearing total knee arthroplasty

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

Summary

ID

NL-OMON49018

Source
ToetsingOnline

Brief title
Posterior stabilized versus mobile bearing total knee arthroplasty

Condition

- Joint disorders

Synonym
knee replacement, Total knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Xpert Orthopedie Amsterdam

Source(s) of monetary or material Support: eigen wetenschappelijke stichting

Intervention

Keyword: Knee flexion, Posterior stabilisation, Range of motion, Total knee arthroplasty

Outcome measures

Primary outcome

The main study parameter is range of motion, measured on a short-leg

radiograph, of the operated knee 1 year postoperative.

Secondary outcome

Other measurements of range of motion (goniometer) and patient reported outcome

measures (KOOS; NRS pain and satisfaction; EQ5D; FJS-12)

Study description

Background summary

Total Knee Arthroplasty (TKA) is a successful procedure and remains the golden standard for treatment of invalidating symptoms of osteoarthritis. Maximal knee flexion and range of motion is one of the parameters that is proven to be highly correlated to patient satisfaction after TKA. It is theorized a mobile bearing posterior stabilized artificial knee offers deeper flexion than its mobile bearing (non-stabilized) counterpart due to the more constrained nature.

Study objective

The main objective is to compare range of motion between a mobile bearing posterior stabilized knee device and its non-stabilized mobile bearing counterpart. Secondary objective is to compare patient reported outcome measures (PROMs) between both knee systems 1 year postoperative.

Study design

Patient blinded, randomized controlled trial.

Intervention

The study group will receive the Advanced Coated System (ACS) mobile bearing posterior stabilized knee system and the control group will receive the ACS mobile bearing (non-stabilized) knee system.

Study burden and risks

All patients will be seen at regular follow-up intervals identical to standard knee arthroplasty protocol at our clinic, with 1 additional visit for the current study. Patients will additionally be asked to undergo measurements of range of motion on the operated side, for which an additional short-leg radiograph is required.

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

- Age between 18-80 years
- BMI<35
- End stage knee osteoarthritis warranting total joint arthroplasty
- In stable health, suitable for surgery, willing and able to participate in the follow-up program.
- Understanding of Dutch/English language.
- Written and signed Informed Consent

Exclusion criteria

- Revision of unicondylar or previous total knee arthroplasty
- Skeletal immaturity
- Charcot joints
- Patellar resurfacing and/or placement of a patellar prosthesis
- Previous high tibial osteotomy
- Rheumatoid arthritis
- Inability to complete the exercises due to contralateral knee osteoarthritis/arthroplasty or hip osteoarthritis/arthroplasty
- Previous arthrofibrosis or pre-operative flexion <90 degrees
- Unable (due to mental and/or cognitive comorbidities) or unwilling to cooperate in the follow¬-up program

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	16-07-2020
Enrollment:	56
Type:	Actual

Medical products/devices used

Generic name:	Total knee arthroplasty
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-04-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL72684.018.20