Knee flexion after two types of knee arthroplasty

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28845

Source
NTR

Brief title
N/A

Health condition

Knee Osteoarthritis

Sponsors and support

Primary sponsor: Mathys Medical Ltd
Source(s) of monetary or material Support: Mathys Medical Ltd

Intervention

Outcome measures

Primary outcome

The primary endpoint of the study is the active flexion at one year.

Secondary outcome

The secondary endpoints are, also measured at one year:

* Knee Society clinical rating scale including:

- Passive range of motion

- AP-laxity of the knee joint in 90 and 25 degrees

- Axial rotation of the lower leg

- VAS-score

- Maximum step height

Study description

Background summary

Jacobs WCH, Christen B, Wymenga AB, Schuster A, van der Schaaf DB, ten ham A, Wehrli U. Functional performance of mobile versus fixed bearing total knee prostheses; a randomised controlled trial. Knee Surg Sports Traumatol Arthrosc 2012;20(8):1450-55.

Study objective

The null hypothesis is that the mobile bearing does not give a greater flexion than the fixed bearing TKP.

Study design

The patients included in the study will be seen at standard follow-up moments. The fixed moments are preoperative, and 3, 6, and 12 months postoperatively.

Intervention

The trial treatments are the balanSysTM fixed and mobile bearing total knee prostheses. The treatments are both CE-marked and currently in use in all trial centers. The device is a surgically invasive, implantable device for long-term use and therefore categorized as Class IIb.

Contacts

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Eligibility criteria

Inclusion criteria

The patient must:

1. Have been diagnosed with osteoarthritis (also referred to as gonarthrosis).

2. Be a candidate for primary total knee arthroplasty for this reason.

3. Be expected to undergo only one arthroplasty procedure in next 12 months.

4. Be willing to attend all the follow-up examinations.

5. Be expected to make a full recovery.

6. Be 60 to 75 years old.

7. Have a pre-operative alignment (varus or valgus) < 10°

8. Have a BMI < 30

9. Be living independently.

Exclusion criteria

The patient must not:

1. Be undergoing revision arthroplasty.

2. Missing or having an insufficient posterior cruciate ligament.

3. Need cementing of the tibial stem due to osteoporosis.

4. Be currently enrolled in a clinical investigation with either a drug or an investigational device or has been enrolled in such an investigation during the last 6 months.

5. Have a history of any allergic reaction to any medical device required for this study.

6. Suffer from heart or lung disease.

7. Have any contraindication to surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2002
Enrollment:	124
Type:	Actual

Ethics review

Positive opinion

Date:	14-04-2008
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	NL1231
NTR-old	NTR1276
Other	: 29
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A