Flexion with the Journey total knee prosthesis (RCT)

No registrations found.

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

Summary

ID

NL-OMON24383

Source
Nationaal Trial Register

Brief title
Journey

Health condition

Patients with noninflammatory osteoarthritis requiring a unilateral total knee replacement.

Sponsors and support

Primary sponsor: Smith and Nephew
Source(s) of monetary or material Support: Smith and Nephew

Intervention

Outcome measures

Primary outcome

- Active Flexion of the knee

Secondary outcome

- Intra- and perioperative data (operative time, blood loss)

- Knee Society Rating System (KSS)

- Patella Scoring System

- UCLA score

- Satisfaction

- Active Flexion standing

- Passive flexion lying down

Study description

Background summary

Period

2002-2013

Participants

- G. van Hellemondt SMK Orthopedic Surgeon

- Dr. J. Victor, St Lucas Brugge, Orthopedic Surgeon

- Dr. J Bellemans, AZ Pellenberg, Orthopedic Surgeon

- Dr. A.B. Wymenga SMK Orthopedic Surgeon

- K. Defoort SMK Orthopedic Surgeon

- W.C.H. Jacobs SMK Health Scientist

Sponsor

Smith and Nephew

Purpose

This is a randomised controlled trial to evaluate the difference between the High Performance and the Genesis II implants. The only design feature is a more natural tibial plateau alignment, which is believed to yield more maximal flexion.

Methodology

Patients are randomised into two groups receiving either the High Performance or the Genesis II prosthesis. Preoperatively and postoperatively, clinical scores as well as functional assessment are obtained. Clinical scores are Knee Society Clinical Rating System and maximal flexion possibilities. Functional scores are the functional score of the Knee Society Clinical Rating System and the patellar score, and UCLA score.

Progress

Medical Ethical Committee approval has been obtained and the first patients have been included and randomized. First postoperative results are being collected. Final inclusions are planned in 2010.

Study objective

The null hypothesis is that the Journey TKP and the Genesis II TKP gives an equal maximal flexion at one year. This hypothesis will be tested two-sided.

Study design

1 year

Intervention

Treatments are primary total knee arthroplasty of the Journey and Genesis II designs, both from Smith & Nephew company. A total knee arthroplasty is a joint replacement treamtent. It contains a lower leg component and an upper leg component and a polyethylene menisci part. The main difference between the two types is in the polyethylene part, which is more natural aligned in the Journey type. A total joint arthroplasty is applied once and remains in situ, so there is no dose relation or treatment time.

Primairy outcome is measured during polyclinical visits, where the patient is asked to flex the knee as much as possible. The maximum flexion is measured with a long leg goniometer.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient presents with noninflammatory osteoarthritis and requires a unilateral total knee replacement.

2. Patient reports moderate to severe pain in affected knee.

3. Patient is 18 40 to 70 years of age, inclusive.

4. Patient is willing to consent to participate in the study by signing and dating an IRB-approved consent form.

5. Patient plans to be available for follow-up through five years postoperative.

6. Patient is in stable health.

Exclusion criteria

1. Patient known to have insufficient femoral or tibial bone stock resulting from concomittant conditions.

2. Patient has a BMI >35.

3. Patient’s expected physical activity after surgery is 2 or less on the UCLA activity scale.

4. Patient has had previous hip or knee replacement surgery in the last 6 months.

5. Patient has had major, non-arthroscopic surgery to the study knee.

6. Patient has an active, local infection or systemic infection.

7. Patient has physical, emotional or neurological conditions that would compromise the patient’s compliance with postoperative rehabilitation and follow-up.

8. Patient has grade 3 collateral ligament insufficiency.

9. Patient has knee flexion < 90°.

10. Patient has fixed flexion deformity >20°.

11. Patient has varus or valgus deformity >10°, unless correctable to under 10°.

12. Patient has an immunosuppressive disorder.

13. Patient is pregnant or plans to become pregnant during the course of the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	122
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-11-2008
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	NL1465
NTR-old	NTR1535
Other	METC (regio Arnhem-Nijmegen) : 2005/074
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A