# Flexion with the Journey total knee prosthesis (RCT)

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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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON24383

**Bron**
Nationaal Trial Register

**Verkorte titel**
Journey

**Aandoening**

Patients with noninflammatory osteoarthritis requiring a unilateral total knee replacement.

### Ondersteuning

**Primaire sponsor:** Smith and Nephew
**Overige ondersteuning:** Smith and Nephew

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

- Active Flexion of the knee

# Toelichting onderzoek

**Achtergrond van het onderzoek**

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.

**Doel van het onderzoek**

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.

**Onderzoeksopzet**

1 year

**Onderzoeksproduct en/of interventie**

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.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-03-2007 |
| Aantal proefpersonen: | 122 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 14-11-2008 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1465 |
| NTR-old | NTR1535 |
| Ander register | METC (regio Arnhem-Nijmegen) : 2005/074 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Resultaten

**Samenvatting resultaten**
N/A