# Early Functional Outcome and Patient Satisfaction In Guided motion vs Conventional Total Knee Arthroplasty

Published: 14-09-2018
Last updated: 12-04-2024

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Joint disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46471

**Source**
ToetsingOnline

**Brief title**
Guided Motion vs Conventional TKA

### Condition

- Joint disorders
- Bone and joint therapeutic procedures

**Synonym**
degenerative knee joint, Gonarthrosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Orthopedium
**Source(s) of monetary or material Support:** Financiering vanuit het Orthopedium

## Intervention

**Keyword:** Arthroplasty, Function, Guided motion, Knee

## Outcome measures

### Primary outcome

Primary objective of this study is to determine differences in short term functional outcome and patients perspective of outcome following Total Knee Arthroplasty between the two different total knee prosthesis, measured using the Oxford Knee Score (OKS).

### Secondary outcome

* Range of motion of the knee measured using a goniometer

* Pain relief, functional abilities, satisfaction and fulfilment of expectations using the Knee Society Score (KSS), KOOS-PS, the Numerical Scale for Pain and Satisfaction (NRS-pain, NRS-satisfaction).

* Overall quality of life using the EQ-5D questionnaire

* The number of adverse events or the need for revision

* The length of hospital stay measured in days

# Study description

### Background summary

Despite substantial advances in primary Total Knee Arthroplasty (TKA) in the recent decades, the level of patient satisfaction one year after surgery (81-89%) shows room for improment and is thought to increase when using guided motion prosthesis designed to mimic natural kinematics. The Journey II BCS is a new implant design which follows the principles of guided motion to reproduce natural knee kinematics. The natural kinematics are claimed to produce superior functional and clinical outcome and thus higher patient satisfaction levels.

We want to perform a randomized control trial with a follow-up of 1 year to compare patient satisfaction and functional and clinical outcomes between the Journey II BCS and the Genesis II total knee prosthesis to determine whether these claims are accurate. We choose the Genesis II prosthesis for our control group because it*s a proven prosthesis with low revision rates, and it*s the most frequent used prosthesis in the Netherlands.

The null hypothesis is that there is no significant difference in short-term patient satisfaction, and functional and clinical outcomes after primary total knee arthroplasy using either the Journey II or the Genesis II prosthesis. This study distinguishes itself from current ongoing studies worldwide, which are all observational studies, by randomizing and comparing the new prosthesis with a widely used and proven prosthesis.

See the appendix in the additional remarks section 'J' for current ongoing trials.

## Study objective

The goal of this study is to determine functional outcome and patient satisfaction between the Journey II and the Genesis II prosthesis. The results of this research will help optimize prosthesis selection, possibly resulting in higher patient satisfaction

## Study design

Prospective, randomised, single centre, single-blinded intervention research

## Intervention

Both groups will undergo total knee arthroplasty. Patients in the intervention group will receive a Journey II prosthesis. Patients in the control group wil receive a Genesis II prosthesis.

## Study burden and risks

Patients will have to fill out above mentioned questionnaires during regular policlinical appointments.Additionally they will be asked to fill out questionnaires pre-operatively and at 24 months post-op. For more information I refer you to chapter 7.8 of the studyprotocol for the schedule of events.

Early single surgeon series have shown that the Journey II is a safe prosthesis which might score better in functional and clinical outcomes when compared to conventionel prosthesis designs. The Journey is CE-marked and roughly 75.000 Journey II prosthesis have been implanted worldwide since 2012. Current data shows revision rates do no significantly differ from national revision rates.

This shows that usage of the Journey II holds no additional risks when compared to conventional total knee arthroplasty.

For the summary of findings from early single surgeon series I refer you to section 5.2 of the studyprotocol.

## Contacts

**Public**
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**Scientific**
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

1. Subject requires primary total knee arthroplasty due to degenerative joint disease
2. Subject is 18-80 years of age and skeletally mature
3. Subject agrees to consent to and to follow the study visit schedule (as defined in the study protocol and informed consent form), by signing the EC approved informed consent form
4. Subject plans to be available through 2 years postoperative follow-up

5. Subject is capable of understanding the Dutch language
6. Subject is able to consent to participate by signing the informed consent form

### Exclusion criteria

1. subject has severe pronation of the ipsilateral foot or any other lower extremity or hip condition causing abnormal ambulation
2. patient has undergone a previous osteotomy or fracture fix
3. subject has active infection or sepsis (treated or untreated)
4. subject has presence of malignant tumor, metastatic, or neoplastic disease
5. subject has conditions that may interfere with the TKA survival or outcome (i.e., Paget*s or Charcot*s disease, vascular insufficiency, severe muscular atrophy, uncontrolled diabetes, severe renal insufficiency or neuromuscular disease)
6. subject has inadequate bone stock to support the device
7. subject has an emotional or neurological condition that would pre-empt their ability or willingness to participate in the study

## Study design

### Design

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

### Recruitment

NL

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2018 |
| Enrollment: | 192 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | Journey II BCS total kneeprosthesis |

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| Registration: | Yes - CE intended use |

## Ethics review

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| Approved WMO Date: | 14-09-2018 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

## 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 | NL63782.098.17 |