A Prospective, Non-randomized, Consecutive Series, Multicenter, Post-Market Study to Evaluate the Clinical Outcome of Total Knee Arthroplasty Using Journey II BCS Total Knee System

Published: 05-03-2014
Last updated: 17-01-2025

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

Summary

ID

NL-OMON55575

Source
ToetsingOnline

Brief title
Observational study of the Journey II BCS Total Knee System

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
cartilage damage, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Smith & Nephew Orthopaedics AG
Source(s) of monetary or material Support: Smith & Nephew Orthopaedics AG

Intervention

Keyword: Clinical Outcome, Efficacy, Safety, Total Knee Arthroplasty

Outcome measures

Primary outcome

Revision for any reason (*revision* will be defined as the exchange of one or

more components)

Secondary outcome

- EQ-5D

- 2011 KSS

- Adverse events

- Radiographic evaluation

Study description

Background summary

The continuous evaluation of the safety and efficacy of medical devices that are brought onto the market by the manufacturer is an obliged quality requirement, imposed by the European Directives. Smith & Nephew (Smith & Nephew Orthopedics AG, Baar, Zwitserland) initiates this study to evaluate the safety and efficacy of the Journey II BCS knee prosthesis with patients who underwent total knee arthroplasty (how well is its performance and to which extent do adverse events occur?) up to 10 years after surgery.

Study objective

The purpose of this study is to document the short-, mid- and long-term safety and efficacy of the Journey II BCS knee prosthesis. The goal of this study is to confirm the safety and efficacy of the Journey II BCS knee prosthesis by

demonstrating non-inferiority of the cumulative percent success in subjects implanted with the JOURNEY II BCS Total Knee System compared to a literature reference rate of 94.3% (AOA annual report 201121) at 10 years. *Success* is defined as 10 year survival of the study device without revision for any reason.
Primary endpoint of the study is therefore "Revision for any reason" and for the purpose of this study, *revision* will be defined as the exchange of one or more components.

Study design

This is a multicenter, prospective, observational study to collect relevant clinical data from 167 patients implanted with the Journey II BCS Knee System. Data from eligible patients, who have provided written and informed consent for the collection of their coded data, will be recorded from the patient*s medical file on specially designed case report forms (CRF*s).

Intervention

Journey II BCS Total Knee System, including patella resurfacing.

Study burden and risks

Patients will not be burden with excessive risks in case of participation. Most of the data will be collected during routine clinical assessments. Patients will be asked to fill out some questionnaires (KSS & EQ-5d) at each visit. Furthermore, they will be asked to visit the clinic at 2, 5 and 10 years after surgery. The advantage is that the patient is followed closely. If for the 5Year follow-up visit, a patient refuses to come to the hospital or is unable to due to COVID-19, a telephone follow-up assessment will be performed as to prioritize safety of patients and study personnel over the study needs.
Next, the patient will be exposed to ionizing radiation due to the X-rays that will be taken from the knee joint. The total effective dose of this radiation is acceptable.
Finally, the information we get from this study may help improve the treatment of people that need to undergo total knee arthroplasty.

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

• subject requires primary total knee arthroplasty with the Journey II BCS Total Knee System, including patella resurfacing
• subject requires primary total knee arthroplasty due to degenerative joint disease (primary osteoarthritis, post-traumatic arthritis, avascular necrosis, rheumatoid arthritis)
• subject is of legal age to consent (>18y), 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

Exclusion criteria

- age > 75 years
- subjects with immunosuppressive disorders
- subject has severe pronation of the ipsilateral foot or any other relevant clinical condition contributing to abnormal ambulation (including but not limited to ankle fusion, ankle arthroplasty, previous hip fracture, ipsilateral hip arthritis resulting in flexion contracture)
- patient has undergone a previous major surgery to the study knee (including but not limited to osteotomy, fracture fix, medial or lateral ligament surgery)

- subject has active infection or sepsis (treated or untreated)
- At the time of enrollment, subject has one or more arthroplasties that are not fully healed and well-functioning, as determined by the investigator
- subject has presence of malignant tumor, metastatic, or neoplastic disease
- subject has conditions that may interfere with the TKA survival or outcome
- subject has inadequate bone stock to support the device (severe osteopenia, family history of severe osteoporosis or osteopenia)
- subject has an emotional or neurological condition that would pre-empt their ability or willingness to participate in the study
- subject has a BMI>40

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-09-2014
Enrollment:	33
Type:	Actual

Ethics review

Approved WMO Date:	05-03-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
Other	ClinicalTrials.gov, Ref Nr: NCT02211794
CCMO	NL46006.048.13