Journey II BCS Observational Study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27958

Source
Nationaal Trial Register

Health condition

total knee arthroplasty
degenerative joint disease

Sponsors and support

Primary sponsor: Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10d
6340 Baar
Switzerland
Source(s) of monetary or material Support: Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10d
6340 Baar
Switzerland

Intervention

Outcome measures

Primary outcome

• Revision for any reason
For the purpose of this study, “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

N/A

Study objective

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.

A non-inferiority test of the cumulative percent success (defined here above) in subjects implanted with the JOURNEY II BCS Total Knee System compared to a literature reference rate will be the primary test of efficacy in this study. The null hypothesis is H0: Pi0 - Pi > or = 0.05 and the alternative hypothesis is Ha: Pi0 -ƒàPi < 0.05.

Study design

Preop

3 Month (± 2W)

1Year (± 2M)

2 Year (± 3M)

5 Year (± 6M)

10 Year (± 6M)

Intervention

Only patients who will be treated with the Journey II BCS knee prosthesis as part of their normally planned care will qualify for this study.

Contacts

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Eligibility criteria

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, 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

• subject plans to be available through ten (10) years postoperative follow-up

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 of the following athroplasties that are not fully healed and well-functioning, as determined by the investigator:

o ipsilateral or contralateral primary total hip arthroplasty or hip resurfacing arthroplasty

o contralateral primary total knee or unicondylar knee arthroplasty

• subject has presence of malignant tumor, metastatic, or neoplastic disease

• subject has conditions that may interfere with the TKA survival or outcome (i.e., Paget’s or Charcot’s disease, vascular insufficiency, muscular atrophy, uncontrolled diabetes, moderate to severe renal insufficiency or neuromuscular disease)

• 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:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	167
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4130
NTR-old	NTR4281

Register	ID
Other	: R11009-7
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A