Journey II BCS Observational Study

Gepubliceerd: 05-12-2013 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27958

Bron
Nationaal Trial Register

Aandoening

total knee arthroplasty
degenerative joint disease

Ondersteuning

Primaire sponsor: Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10d
6340 Baar
Switzerland
Overige ondersteuning: Smith & Nephew Orthopaedics AG
Oberneuhofstrasse 10d
6340 Baar
Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Revision for any reason
For the purpose of this study, “revision” will be defined as the exchange of one or more components.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

Preop

3 Month (± 2W)

1Year (± 2M)

2 Year (± 3M)

5 Year (± 6M)

10 Year (± 6M)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Belgium
0032 2 702 29 85

Wetenschappelijk

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Belgium
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	167
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4130
NTR-old	NTR4281
Ander register	: R11009-7
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A