Flexion with the Journey II BCS TKA

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29583

Source
NTR

Brief title
Flexion with Journey II

Health condition

non-inflammatory knee osteoarthritis
primary total knee arthroplasty

knie artrose
primaire knieprothese

Sponsors and support

Primary sponsor: St Maartenskliniek Nijmegen
Source(s) of monetary or material Support: Smith & Nephew

Intervention

Outcome measures

Primary outcome

Maximal passive knee flexion measured on a lateral X-ray one year after surgery.

Secondary outcome

Clinical, functional and radiological performance as measured with: active flexion (lying and standing), KSS, EQ-5d, KOOS, Kujala, Forgotten Joint Score, VAS Satisfaction, number and type of Adverse Events, Hip-Knee-Ankle angle, Patellar tilt & displacement.

Study description

Background summary

Rationale: The Journey II BCS claims a renewed right to an active lifestyle by delivering unmatched function, motion and durability through natural motion in TKA. Natural motion will result into high flexion ability. The range of knee flexion and maximum knee flexion influences a patient's ability to perform important activities of daily living and may therefore directly influence overall quality of life. When this new knee system will facilitate a high knee flexion, this will be depicted in a superior knee function. In addition, a high flexion ability will result in high clinical and functional outcome scores and high patient satisfaction.

Objective: The primary objective of the study is to investigate the maximal flexion ability of the Journey II BCS total knee system one year after surgery.

The secondary objective is to assess patient satisfaction, clinical, functional and radiological performance up to two years.

The ultimate goal is to compare the clinical and functional results of this cohort with the cohorts in the Journey I BCS and Genesis II RCT.

Study design: A prospective, non-randomized, consecutive series, observational study.

Statistical analysis: The primary outcome will be evaluated using descriptive statistics. Thereafter, the three cohorts will be compared using ANOVA.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients participating in this study will not being barred by any additional risk other than the regular risks for a surgery of a primary TKA. The patients will visit the clinic at regular follow-up moments up to one year, and will receive a reimbursement for the two year visit. These visits take ±30 min extra than regularly because at these moments the patient visits also the research nurse for data collection. The questionnaires and physical

examinations of the knee do not bring any extra burden. The additional radiographic assessment (long leg X-ray at 3 months and X-rays at two year visit) increases the total amount of radiation only slightly. However, the total amount of radiation falls within the limits of the ICRP (International Commission of Radiological Protection).

NOTE: some of the patients will additionally participate in a large sponsor-initiated European multi-centre observational safety and efficacy study.

Study objective

When this new knee system will facilitate a high knee flexion, this will be depicted in a superior knee function. In addition, a high flexion ability will result in high clinical and functional outcome scores and high patient satisfaction.

Study design

pre-operative, 3 months, 12 months, 24 months.

Intervention

The trial treatment is the Journey II BCS Total Knee System, which has been cleared for use by the FDA through the 510(k) process in the US and has been CE-marked in Europe.

All patients will receive associated hospital preoperative, per-operative and postoperative standard care.

The Journey II BCS replacement procedures will be performed according to the recommended surgical technique described in the instructions for use as a means of preparing the bones for the implants. The instrumentation consist of femoral and tibial cutting blocks, placed with the use of intramedullary or extramedullary alignment rods. The Journey II BCS total knee system will be placed with the use of a tensioner and by means of a fully cemented femoral and tibial component. For this study, the patella must be resurfaced.

Contacts

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Eligibility criteria

Inclusion criteria

•Patient presents with non-inflammatory knee osteoarthritis (radiologically confirmed), requiring total knee arthroplasty

•Patient is 40 to 70 years of age, inclusive

•Patient plans to be available for follow-up through two years postoperative

•Patient is in stable health and is free of or treated for cardiac, pulmonary, haematological, or other conditions that would pose excessive operative risk

•Patient has <10□ fixed (non-correctable) varus or valgus deformity

•Orthopaedic surgeon is member of the Knee Reconstruction Unit

Exclusion criteria

•Patient is known to have insufficient femoral or tibial bone stock

•Patient has a BMI >35

•Patient's expected physical activity after surgery is 2 or less on the UCLA Activity Scale

•Patient has had previous hip or knee replacement surgery in the last 6 months

•Patient is planned to have additional hip or contralateral knee replacement in the next 6 months

•Patient has had major, non-arthroscopic surgery to the study knee, including osteotomy around the knee

•Patient has an active, local infection or systemic infection

•Patient has physical, emotional or neurological conditions that would compromise compliance with postoperative rehabilitation and follow-up

•Patient has grade 3 collateral ligament insufficiency (complete tear of ligament)

•Patient has knee flexion <90□

•Patient has fixed flexion deformity >20□

•Patient has rheumatoid arthritis, any autoimmune disorder or immunosuppressive disorder

•Patient is pregnant or plans to become pregnant during course of study

•Patient has a known sensitivity to materials in the device and/or cutting blocks

•Patient has >30□ extension deficit

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):	01-10-2014
Enrollment:	62
Type:	Anticipated

Ethics review

Positive opinion

Date:	31-07-2014
Application type:	First submission

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	NL4352
NTR-old	NTR4709
Other	: P1368 Reade METC

Study results