Primary stability of fully cemented LEGION HK Hinge Knee System in revision total knee arthroplasty measured with RSA

Published: 01-11-2016
Last updated: 15-05-2024

The primary objective of this study is to investigate the stability of the fixation in the bone of the Legion HK Hinge Knee System in revision TKA. The secondary objective of this study is to assess the functional performance/ effectiveness (…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON45618

Source
ToetsingOnline

Brief title
Legion Hinged RSA

Condition

- Bone and joint therapeutic procedures

Synonym
Stability of the fixation in the bone; functional performance

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Smith & Nephew Ltd.

Intervention

Keyword: fully cemented fixation, Hinged revision total knee arthroplasty, radiostereometric analysis, stems

Outcome measures

Primary outcome

The primary endpoint of the study is the stability of the implant fixation in

the bone at two years. Stability is measured and will be described by migration

of the implant with regard to the (RSA markers in the) bone.

Secondary outcome

To assess the functional performance of the Legion HK as revision TKA a set of

Patient-Reported Outcome Measures (PROMs) as well as Clinician Reported Outcome

Measures (CROMs) will be used.

- Knee Society Score

- Oxford Knee Score

- KOOS-PS

- VAS pain and VAS satisfaction

- Adverse Events

Study description

Background summary

As the number of primary total knee replacements increases annually, the need for a good revision of a total knee arthroplasty (TKA) likewise will increase exponentially. Hinged-type revision TKA systems are used with stems, the

prosthesis components are always cemented, whereas the stems can be placed cemented or uncemented. Currently, the fully cemented (component placed cemented, stems placed cemented) Legion HK system is used in the Sint Maartenskliniek (SMK). Whether this construct in these patients results in adequate stable and safe fixation of the implant in the bone, remains to be investigated. World-wide this will be the first RSA study on a (fully cemented) hinged-type revision TKA.

Study objective

The primary objective of this study is to investigate the stability of the fixation in the bone of the Legion HK Hinge Knee System in revision TKA. The secondary objective of this study is to assess the functional performance/ effectiveness (clinical results) of the Legion HK Revision Total Knee Arthroplasty System.

Study design

The study will be a cohort study involving a total of twenty patients. Participants will be assessed on 7 occasions (pre-op, operation/post-operative, and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-surgery). The measurements at pre-operative, 6 months and 2 years do not coincide with standard care visits. The study ends at 2 years follow-up.

Intervention

The study intervention is the fully cemented hinged-type revision TKA as used in regular clinical practice.

Study burden and risks

The extra amount of time over the two years that a patient invests in the study is about seven hours. There is no additional risk other than the regular risks for a surgery of a revision TKA. The questionnaires and physical examinations of the knee do not bring any extra burden and the additional radiological assessments have a total amount of radiation that leads to a very small extra risk.

Contacts

Public
Sint Maartenskliniek

Hengstdal 3

Ubbergen 6574 NA
NL
Scientific
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574 NA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient requires a revision total knee replacement and the Legion HK system is indicated in this patient.
- Patient is willing to consent to participate in the study by signing and dating an IRB-approved consent form.
- Patient plans to be available for follow-up through two years postoperative.
- Patient is in stable health and is free of or treated and stabilized for cardiac, pulmonary, haematological, or other conditions that would pose excessive operation risk.

Exclusion criteria

- Patient has a BMI >40.
- Patient has an active, local infection or systemic infection.
- Patient is unable to come/return to the hospital or has physical, emotional or neurological conditions that would compromise the patient's compliance with postoperative rehabilitation and follow-up (e.g.: drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson, Multiple sclerosis, etc.).
- Patient has an immunosuppressive disorder (chronic condition characterized by markedly inhibited ability to respond to antigenic stimuli.) Examples of such conditions include patients

who are on immunosuppressive therapy (corticosteroid hormones in large amounts, cytotoxic drugs, antilymphocytic serum or irradiation in large doses), patients with acquired immunodeficiency syndrome (AIDS) or auto-immune diseases (including inflammatory arthritis).
- Patient has a known sensitivity to materials in the device.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Legion HK Hinge Knee System (fully cemented)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-11-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-12-2017
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

ID: 29248
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58887.048.16
OMON	NL-OMON29248