

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

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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 (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Bone and joint therapeutic procedures
<b>Study type</b>	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

## 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