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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29248

Source
Nationaal Trial Register

Brief title
Legion Hinged RSA

Health condition

revisie totale knie arthroplastiek

volledig gecementeerde fixatie

radiostereometrische analyse

revision total knee arthroplasty

fully cemented fixation

radiostereometric analysis

Sponsors and support

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

Intervention

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-Rported 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

Participants will receive the Legion HK Revision Total Knee Arthroplasty System which is commercially available and has a CE mark (Legion HK System, Smith & Nephew Ltd).

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 outcomes:

To assess the functional performance of the Legion HK as revision TKA a set of Patient-Rported 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 design

- Pre-operative

- Post-operative

- after 6 weeks

- after 3 months

- after 6 months

- after 12 months

- after 24 months

Intervention

Participants will receive the Legion HK Revision Total Knee Arthroplasty System which is commercially available and has a CE mark (Legion HK System, Smith & Nephew Ltd).

Contacts

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Eligibility criteria

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 operative risk.

Exclusion criteria

• Patient has a BMI >35.

• Patient has an active, local infection or systemic infection.

• Patient with a prosthetic joint infection as indication for a total knee revision

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45618
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6230
NTR-old	NTR6410
CCMO	NL58887.048.16
OMON	NL-OMON45618

Study results

Summary results
n/a