Construct stability with the use of cones in revision total knee arthroplasty measured with RSA

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

Summary

ID

NL-OMON52619

Source
ToetsingOnline

Brief title
Cones RSA

Condition

- Bone and joint therapeutic procedures

Synonym
degenerative joint disease, knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Smith & Nephew;Inc.,Smith&Nephew, Inc

Intervention

Keyword: Cones, Radiostereometric analysis, Revision total knee arthroplasty

Outcome measures

Primary outcome

The primary endpoint of this study is the stability of the revision construct

with cones at two and five years. Stability is measured and will be described

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

Secondary outcome

The secundary endpoint is the survival of the revised TKA system. Additionally,

clinical and functional performance will be evaluated.

Study description

Background summary

In (re-)revision total knee arthroplasty (TKA), cones can be used to ensure sufficient fixation of the revision construct in the bone in cases with suboptimal metaphyseal bone stock. Together with press-fit placed stems of sufficient length cones can reduce interface stresses of damaged bone in the distal femur or proximal tibia and provide additional prosthetic surface for implant fixation. Whether this construct in revision cases results in adequate stable and safe fixation of the implant in the bone, remains to be investigated. With radiostereometric analysis (RSA) it is possible to investigate the stability of the construct in a very accurate way.

Study objective

The primary objective of this study is to investigate the stability of the fixation in the bone of the use of the Legion prosthesis with cones in revision TKA, until 5 years postoperatively. The secondary objective of this study is to assess the survival of the Legion revision TKA with cones.

Study design

Prospective cohort study.

Intervention

The study intervention is the hybrid fixation of Legion revision TKA with cones as used in regular clinical practice.

Study burden and risks

The extra amount of time over the five 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. The additional radiological assessments have a total amount of 24 µSv radiation, which is a neglectable extra risk considering the background radiation of 2 mSv per year in the Netherlands.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Patients requiring a (re-(re-))revision of their total knee arthroplasty and the Legion system with the use of a cone in the tibia because of metaphyseal bone loss.
• Patient is willing to consent to participate in the study.
• Patient is <78 years old
• Patient plans to be available for follow-up through five years post-operative.
• 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 (< ASA II).

Exclusion criteria

• Indication for a hinged-type revision system.
• Active, local infection or systemic infection.
• Patient has physical, emotional, or neurological conditions that would compromise the patient*s compliance with postoperative rehabilitation and follow-up.
• Patient has an immunosuppressive disorder (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):	24-10-2019
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Legion Revision Knee System with Cones
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-11-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-06-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL66833.091.18