Performance of MRK, NexGen and LCS Total Knee Prosthesis based on AP Stability Measurement and PROMS

Published: 09-04-2015
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Primary objective:Is there a significant difference in Anterior/Posterior stability between MRK, LCS and NexGen total knee prosthesis 1 year post-op?Secondary objectives:Is there a relevant correlation between Anterior/Posterior stability and...

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

Summary

ID

NL-OMON46917

Source
ToetsingOnline

Brief title
Multicenter study AP-stability TKP

Condition

- Bone and joint therapeutic procedures

Synonym
knee stability

Research involving
Human

Sponsors and support

Primary sponsor: Antonius Ziekenhuis, Sneek
Source(s) of monetary or material Support: BdH Medical BV,eigen budget deelnemende ziekenhuizen

Intervention

Keyword: kneelax, multicenter, stability, TKR

Outcome measures

Primary outcome

Main study parameter/endpoint:

Measurement with Kneelax device will provide comparison in anterior/posterior displacement (laxity) of the replaced joint at 30, 60 and 90 degrees angle.

With these measurements the three prosthesis will be compared. This measurement will take place once: 12 months post-op. Kneelax is a validated device for measuring such displacement. Measurement will take place in hospital under supervision of a trained physical therapist.

A difference of 2 mm A/P stability is determined as relevant.

Secondary outcome

Secondary study parameters/endpoints

Satisfaction and patient outcome scores (PROMS) and functional scores will be assessed pre-operatively, and post-operatively at 12 months and at 2 years (optional) by questionnaires. This will be assessed using following methods;

PRE-OP:

* Visual Analogue Scale (VAS) for pain at rest and during activity. Note: validated test

* Visual Analogue Scale (VAS) for stability.

* EQ-5D . Note: validated test

* Knee Injury and Orthoarthritis Score (KOOS). Note: validated test

* Oxford Knee score. Note: validated test

* Knee Society Clinical Rating System (KSCRS). Note: validated test

* Kujala Anterior Knee Pain Score. Note: validated test

POST-OP:

* Visual Analogue Scale (VAS) for pain at rest and during activity. Note:

validated test

* Visual Analogue Scale (VAS) for stability

* EQ-5D. Note: validated test

* Knee Injury and Orthoarthritis Score (KOOS). Note: validated test

* Oxford Knee score. Note: validated test

* Satisfaction score; *would you do it again? (VAS). Note: validated test

* Knee Society Clinical Rating System (KSCRS). Note: validated test

* Kujala Anterior Knee Pain Score. Note: validated test

Study description

Background summary

This study aims to distinguish relevant differences between three well established types of prosthesis regarding anterior/posterior stability; Medial Rotation Knee, MRK (Matortho, UK), LCS (Depuy, UK, USA) and Nexgen (Zimmer, USA). Data derived from the study will give new insight in relevant different behaviour of prosthesis mentioned above and will lead to better understanding of improving patient satisfaction in total knee arthroplasty.

Study objective

Primary objective:
Is there a significant difference in Anterior/Posterior stability between MRK, LCS and NexGen total knee prosthesis 1 year post-op?

Secondary objectives:
Is there a relevant correlation between Anterior/Posterior stability and Patient Outcome?
Is there a difference regarding Patient Outcome between MRK and LCS or NexGen total knee prosthesis?

Study design

General
This study is a blind randomised, multi-centre clinical study. The study will include three centres and five surgeons. Each centre will recruit a minimum of 100 patients over a period of maximum 18 months. Each patient will be randomised to receive either:
* MRK or LCS (2 centres)
* MRK or Nexgen (1 centre)
Total cohort of patients will therefore exceed 300 implants. All surgeons will implant relevant amount of the type of prosthesis involved before including data into the study to overcome effect of bias due to *learning curve*. At present time (before start study) all hospitals are already experienced with the prosthesis involved.

Length of Study
Individual study patients will be seen for at least 2 years after surgery. The enrolment period is expected to be 1 to 2 years or until the required sample size is reached. Measurements to encounter the primary objective will be conducted 1 year post-op.

Patient Selection Criteria
In general the patients for the study will be selected out of those who are eligible for total knee replacement due to arthrosis of the knee joint. The Investigator is responsible for evaluating each patient against applicable criteria and assuring that the patient meets the requirements to be enrolled in this clinical investigation. Each patient enrolled in this investigation must meet inclusion criteria and have none of the exclusion criteria.

Intervention

Patients who are included in study will receive a total knee replacement which they were about to receive anyway. Standard surgical procedure and rehab programme will be followed which is not influenced by the study. The

measurement 1 year post-op with the Kneelax device is non-invasive and will be conducted by involved and trained physiotherapists. Additional strain on the joint when measured is carefully controlled and side effects are not expected in any way. All other tests and research consists of questionnaires which be asked to perform on routine visits of patients to the clinical sites.
Intervention is therefore only present regarding the process of randomization.

Study burden and risks

No additional risks are associated with participation in the study. Patients who are included in study will receive a total knee replacement which they were about to receive anyway. Standard surgical procedure and rehab programme will be followed which is not influenced by the study. The measurement 1 year post-op with the Kneelax device is non-invasive and will be conducted by involved and trained physiotherapists. Additional strain on the joint when measured is carefully controlled and side effects are not expected in any way. All other tests and research consists of questionnaires which be asked to perform on routine visits of patients to the clinical sites.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients requiring a knee replacement as determined jointly by the surgeon and the patient
* Over 18 years of age at time of surgery
* Patients who understand the conditions of the study and are willing to participate for the length of the prescribed term of follow-up.
* Patients who are capable of, and have given, informed consent to their participation in the study

Exclusion criteria

* Patients lacking capacity to or who will not provide consent
* Severe muscular, neurological or vascular deficiencies which compromise the affected extremity
* Bone deficiency or deficient bone quality likely to compromise the implant (as determined by surgical team on pre-operative radiographs)
* Severe ligament instability
* Hypersensitivity to the materials used
* Alcoholism or other addictive disorders
* Sepsis
* Osteomyelitis
* Osteomalacia
* Severe Osteoporosis * clinical judgement
* Metabolic disorders which may impair bone formation
* Non correctable flexion contractures >20 degrees
* Varus/valgus deformities >15 degrees
* Those whose prospects for a recovery to independent mobility would be compromised by known pre-existing medical conditions

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2015
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	Total knee replacement; MRK;LCS and NexGen
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-04-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL52316.044.15
Other	volgt nog