Inducible Displacement in Total Knee Prostheses

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

Summary

ID

NL-OMON42998

Source
ToetsingOnline

Brief title
Inducible Displacement

Condition

- Bone and joint therapeutic procedures

Synonym
aseptic loosening, imlant migration

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: RSA-core;rest overheidsgeld

Intervention

Keyword: Aseptic loosening, Implant migration, Inducible Displacement, Total knee prostheses

Outcome measures

Primary outcome

Inducible displacement expressed in mm (translations) and degrees (rotations)

measured during the peak-force application of the different loading regimes.

Secondary outcome

The association of the measured induced displacement of the tibial tray

relative to the bone -expressed in translations (mm) and rotations (degrees)-

with the measured longitudinal migration data to identify which combination of

loading regimes (i.e. force applied versus non-weight bearing examinations)

yields the best discrimination between potentially loose and properly fixed

implants.

Study description

Background summary

Total Knee Replacement (TKR) is one of the most performed orthopedic procedures worldwide. If successful, TKR provides pain reduction and restores the function of the joint. Migration of orthopaedic implants can be assessed with sub-millimetre accuracy using radiostereometric analysis (RSA) and early migration can be used as a predictor of later aseptic loosening. In addition to migration analysis, RSA could also give valuable results measuring *inducible displacement*, which can be defined as the reversible motion of the prosthesis with respect to the bone as a result of applying a force to the prosthesis. For individual patients, measuring inducible displacement could potentially provide clinical evidence of a deteriorating bone-implant or bone-cement interface and therefore a heightened risk of aseptic loosening.

Study objective

The primary objective of this study is to assess in a safe and controlled manner the optimal loading regime for inducing displacement. The secondary objective is to assess the association between inducible displacement and longitudinal migration, and subsequently to identify the loading regime best suited to discriminate between loose and fixed prostheses.

Study design

Case control study

Study burden and risks

To guarantee patient safety, all tasks performed by patients in this study will be accompanied by the coordinating investigator and an experienced radiology assistant. All tasks patients will be asked to perform will be exercises that match activities in everyday living. Patients will be given clear instructions and examples of how to perform the tasks, but will also be told to use their own insight and limitations meaning that patients can indicate if they feel that a certain task will provide difficulties and never over-exert themselves.
The effective radiation dose per RSA-radiograph is 3 µSv. Per patients, six RSA-radiographs will be taken: one supine and one non-weight bearing standing reference examination, and four *inducible displacement* examinations. This means the total radiation dose for patients participating in this study will be
6 x 3 µSv = 18 µSv or 0.018 mSv
According to the guidelines of the European Commission the radiation dose falls in category I, and can be considered trivial.

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 will be included if
• they underwent TKR for primary as well as secondary gonarthrosis as long as the indication for surgery is clearly specified
• a minimal set of patient characteristics (age, gender, BMI, co-morbidity) and disease characteristics (radiological severity, knee function and alignment, status of other knee or hip joints, previous surgeries of the affected knee) is available.
• they are at least *up to date* in terms of follow-up of their respective study (i.e. the most recent examination was less than a year ago and patients have a post-operative examination)
• they participated for at least three years in their respective study and have a usable MTPM-value (i.e. >= 3 bone-markers can be consistently matched with the reference-examination with a CN < 120 over the most recent two years of follow-up
• their standard RSA data meets the criteria as mentioned in the ISO-standard
• they are willing to participate and able to perform the 4 pre-set tasks for the inducible displacement measurements

Exclusion criteria

Patients will be excluded from participation if they do not meet the inclusion criteria, or if they already underwent revision surgery of their TKR since the start of the study they were enrolled in.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	03-11-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-05-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL58105.058.16