Inducible Displacement in Total Knee Prostheses

Gepubliceerd: 25-03-2020 Laatst bijgewerkt: 13-12-2022

TKR with large migration in the last 2 PO years show a larger inducible migration compared with TKR with little to no migration in the last 2 PO years

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21288

Bron
NTR

Verkorte titel
TBA

Aandoening

osteoarthritis; reumatoid arthritis for which TKA is performed

Ondersteuning

Primaire sponsor: LUMC is the sponsor of the study
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Maximum Total Point Motion (MTPM) in the 6 different RSA acquisitions positions

Toelichting onderzoek

Achtergrond van het onderzoek

Total Knee Replacement (TKR) is one ofthe most performed orthopedic procedures worldwide. If successful, TKR provides pain
reduction and restores the function ofthe 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

Doel van het onderzoek

TKR with large migration in the last 2 PO years show a larger inducible migration compared with TKR with little to no migration in the last 2 PO years

Onderzoeksopzet

Single timepoint

Onderzoeksproduct en/of interventie

RSA acquisitions during 6 different positions of the operated knee to assess the induced migration

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 apost-operative examination)
• they participated for at least three years in their respective study and have a usable MTPM-value (i.e. >_ 3 bonemarkers
can be consistently matched with the reference-examination with a CN < 120 over the most recent iwo
years of fol low-u p
• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	05-07-2017
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	25-03-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8487
Ander register	METC-LDD, previously CME-LUMC : P16.156; ABR NL58105.058.16

Resultaten