Differences in diagnosis between weight-bearing and non-weight-bearing conditions in low-field MRI (0.25T) for the diagnosis of patients with instability, patellofemoral problems and component loosening after primary total knee arthroplasty: a feasibility study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON46504

Source
ToetsingOnline

Brief title
Diagnostic value weight-bearing low-field MRI after TKA

Condition

- Joint disorders

Synonym
Problematic total kneeprosthesis/ complaints total knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Pioneers in Health Care

Intervention

Keyword: Component loosening, Instability, Patellofemoral maltracking, Total knee arthroplasty, Weight-bearing MRI

Outcome measures

Primary outcome

The main study parameters for assessing patellofemoral maltracking are patellofemoral indices which are used for assessing patellar height and medial-lateral patellar displacement. For the statistical analysis, a within subject analysis is performed. The main study parameters for assessing component rotation are angle measurements which are used for assessing femoral and tibial component rotation. The assessment of soft tissue deformities will be performed by a segmentation of the structures of interest and comparing the volume and length of these structures with the knee in extension and multiple angles of flexion. For the statistical analysis, a within subject analysis is performed in which the structures will be visually inspected.

The main study parameter to assess component loosening is the amount of fluid in the knee around the knee prosthesis. It is expected that compared to the control group patients with suspected component loosening have an increased amount of fluid around the kneeprosthesis.

Secondary outcome

Secondary endpoints are the inter-observer agreement and intra-observer agreement. These are calculated using the Cohen*s kappa coefficient. The results of two researchers will be included for these calculations.

Study description

Background summary

Total knee arthroplasty is a promising surgical procedure. However, around 20% of the patients report to be dissatisfied. Among the main causes for revision surgery are instability, amongst others caused by soft tissue deformities, patellofemoral complaints and component loosening. It is important to determine the specific causes for these types of complaints to effectively treat them. However, no objective diagnosis methods exist for specifying these types of pathologies. Recent studies conclude that these types of pathologies mainly arise during weight-bearing and knee bending activities. Recently, a low-field MRI system was introduced which offers the possibilities to scan the patient in weight-bearing position and non-weight-bearing position with the knee in multiple angles of flexion. This study explores the relevance of diagnosing instability, patellofemoral maltracking and component loosening in weight-bearing, knee extension, and non-weight-bearing, knee extension and multiple angles of flexion, position in low-field MRI. Therefore, 8 subjects with the aforementioned types of complaints will be scanned during this study. In order to assess the MRI scans of the subjects with complaints, the same scan protocol will be applied to 8 subjects with knee prosthesis without any complaints. The study parameters of the MRI scans from the subjects with complaints will be compared to the study parameters of the MRI scans from the subjects without complaints.

Study objective

The primary objective of this study is to compare weight-bearing and non-weight-bearing low-field MRI scans of patients with instability, patellofemoral maltracking and suspected component loosening after primary total knee arthroplasty. The secondary objective is to compare non-weight-bearing low-field MRI scans of the patient*s knee in extension and multiple angles of flexion of patients with instability and patellofemoral maltracking related complaints after primary total knee arthroplasty.

Study design

A pilot study with sample size of 16 subjects will be carried out. This number

will be divided in 8 subjects with complaints and 8 subjects without complaints.

Study burden and risks

Participation to this research takes approximately 2.5 hours of the subject*s time, in addition to the possible regular care. The risk associated with performing MRI examinations with patients with knee prosthesis is heating. However, since this risk is already small in clinical high-field (1.5T) MRI, the risk will be even smaller in low-field (0.25T) MRI. To perform the weight-bearing scan, the participant needs to stand still for at most 15 minutes. During rotation of the MRI scanner to this position, the participant might experience some dizziness. If this happens, the rotation of the MRI scanner can be aborted immediately and the participant will be turned back to horizontal position. Participation in this research has no consequences for the regular care of the patient.

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

- Subject has a posterior stabilized knee prosthesis with a femur component made of Co-Cr-Mo, a tibia component made of Ti-6Al-4V, a polyethylene liner and optionally a polyethylene patella button
- Patient has signed informed consent
- Patient is older than 18 years

Exclusion criteria

- Patient has an inability to stand for 15 minutes, without assistance
- Patient is not eligible for MRI, based on MRI screening questionnaire
- Pregnancy
- The knee of the patient does not fit in the RF knee coil

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):	25-06-2018
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2018
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-01-2019
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29262
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64460.044.17
OMON	NL-OMON29262