Relation between femoral Component Rotation And Clinical outcomes in total Knee replacement (CRACK). A prospective observational study

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

Summary

ID

NL-OMON55865

Source
ToetsingOnline

Brief title
CRACK

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
knee replacement, Total knee prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: Kosten voor CT scans worden intern door afdeling OK voldaan.

Intervention

Keyword: Rotation, Total knee prosthesis

Outcome measures

Primary outcome

The primary endpoints of this study are (1) the change from baseline PROMs at

1-year follow-up, and (2) the degree of femoral, tibial and combined component

rotation.

The following PROMs will be used:

- Oxford Knee Score (OKS);

- Knee Injury and Osteoarthritis Outcome Score (KOOS);

- EQ-5D;

- VAS pain.

In addition, we will use the clinician-administered American Knee Society Score

(AKSS).

Secondary outcome

Secondary endpoints include the range of motion, and early revision because of

malposition.

Study description

Background summary

Total knee replacement (TKR) for osteoarthritis results in a satisfactory outcome in the majority of patients. However, there is a large subgroup of patients who are dissatisfied with the outcome and report persistent pain. Potentially, surgically modifiable mechanical causes that can be modified during surgery, such as component loosening, malalignment, and instability, contribute to persistent pain.
Previous studies suggest that component malrotation could be the cause for persistent pain and patellofemoral problems, but comprised a small number of patients, and did not use PROMs. Therefore, a large prospective study is needed to identify optimal rotational component alignment.
Our hypothesis is that there is a correlation between femoral and tibial component rotation and functional outcomes as assessed with patient reported outcomes.

Study objective

The aim of this prospective observational study is to assess the relation between femoral component rotation and patient reported outcomes in a large group of patients, and to define a clear cut-off point for revision for malrotated components.
The aim of the substudy is to verify whether rotation of the prosthesis is determined by the anatomical rotation of the knee preoperatively, and secondary whether this affects clinical results.

Study design

Single-center, prospective cohort study, invasive observational, and without intervention.

Study burden and risks

A radiation dose (approximately 0.12 mSv) is associated with CT, which is considered a negligible risk. Since follow-up moments are in line with follow-up according to standard care, this will not result in additional burden on patients.

Contacts

Public
Deventer Ziekenhuis

Nico Bolkesteinlaan 75
Deventer 7416SE
NL

Scientific
Deventer Ziekenhuis

Nico Bolkesteinlaan 75
Deventer 7416SE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Knee osteoarthritis;
- Informed consent for the surgical procedure;
- Signed informed consent for the study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Contra-indication for joint replacement surgery in general (pregnancy, active infection, severe cardiac and respiratory comorbidities);
- Previous distal femoral or proximal tibial fracture resulting in an altered anatomy;
- Previous osteotomies around the knee resulting in altered anatomy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-06-2019
Enrollment:	500
Type:	Actual

Medical products/devices used

Generic name:	Total knee prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-03-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-05-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-09-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	13-01-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 23362
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68333.075.18