Relation between Component Rotation And Clinical outcomes in total Knee replacement

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23362

Source
Nationaal Trial Register

Brief title
CRACK

Health condition

Primary knee joint osteoarthritis

Sponsors and support

Primary sponsor: Deventer Hospital
Source(s) of monetary or material Support: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Intervention

Outcome measures

Primary outcome

The change from baseline OKS at 1-year follow-up in relation to femoral, tibial, and combined component rotation.

Secondary outcome

Additional outcome measures include the Knee Injury and Osteoarthritis Outcome Score (KOOS), EQ-5D, VAS pain, the new American Knee Society Score (KSS, version 2011), knee joint range of motion, and complications (i.e. infection).

Study description

Background summary

Total knee replacement (TKR) for osteoarthritis results in a satisfactory outcome in the majority of patients, although up to one in five patients may be dissatisfied with the outcome. Persistent pain is a main contributor to patient dissatisfaction, and femoral and tibial component malrotation have been identified as a potential cause for both persistent pain and patellofemoral problems. Based on the assumption that component malrotation is the causative factor for persistent pain, early revision for patients with symptomatic malrotated components has been advocated in the literature. However, convincing evidence that component malrotation indeed causes less than optimal outcomes is lacking. This study aims to assess the relation between femoral, tibial, and combined 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.
In this single-center, prospective observational cohort study, a total of 500 patients will undergo total knee replacement. All patients will have a 3D-CT assessment of femoral and tibial component rotation within 8 weeks after surgery. Outcome measures will include the Oxford Knee Score (OKS), Knee Injury and Osteoarthritis Outcome Score (KOOS), EQ-5D, VAS pain, the new American Knee Society Score (AKSS), knee joint range of motion, and complications. We will assess the relation between femoral, tibial, and combined component rotation and PROMs at 8 weeks and 1-year follow-up, and we will determine a cut-off point for the degree of component rotation that results in the best clinical outcomes.

Study objective

We hypothesize that there is a correlation between femoral, tibial, and combined component rotation and functional outcomes as assessed with PROMs.

Study design

Pre-operative, 8 weeks and 1-year post-operative.

Intervention

Total knee replacement

Contacts

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Eligibility criteria

Inclusion criteria

- All mentally competent adult patients who will be treated with total knee replacement for primary knee osteoarthritis (Kellgren and Lawrence grade III or IV);
- Informed consent for the surgical procedure;
- Signed informed consent for the study.

Exclusion criteria

- Contra-indication for joint replacement surgery in general (pregnancy, active infection, severe cardiac and/or respiratory comorbidities);
- Previous distal femoral or proximal tibial fracture resulting in an altered anatomy;
- Previous osteotomies around the knee resulting in an altered anatomy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
NA

Ethics review

Positive opinion

Date:	01-04-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55865
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7635
CCMO	NL68333.075.18

Register	ID
OMON	NL-OMON55865

Study results