# Relation between Component Rotation And Clinical outcomes in total Knee replacement

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON23362

**Bron**
Nationaal Trial Register

**Verkorte titel**
CRACK

**Aandoening**

Primary knee joint osteoarthritis

### Ondersteuning

**Primaire sponsor:** Deventer Hospital
**Overige ondersteuning:** This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

Total knee replacement

# Contactpersonen

## Publiek

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## Wetenschappelijk

Deventer Hospital
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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-05-2019 |
| Aantal proefpersonen: | 500 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nee

**Toelichting**
NA

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 01-04-2019 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55865
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7635 |
| CCMO | NL68333.075.18 |
| OMON | NL-OMON55865 |

# Resultaten