# A Cement Compression Device for Cemented TKA

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| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON25335

**Bron**
NTR

**Verkorte titel**
CCD-TKA

**Aandoening**

Knee osteoarthritis, knee wear

### Ondersteuning

**Primaire sponsor:** Vakgroep Orthopedie RdG
**Overige ondersteuning:** Vakgroep Orthopedie RdG

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The main study parameters are the penetration and distribution of the cement into the bone of the proximal tibia, measured with CT.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Aseptic loosening is a common problem in joint arthroplasty and one of the most common indications for revision arthroplasty in total knee arthroplasty (TKA).

Aseptic loosening occurs mostly at the tibia component and might be caused by suboptimal fixation of the prosthesis. Knee protheses fixated with bone cement (polymethylmethacrylaat = PMMA) have equally good or even better results regarding aseptic loosening and clinical outcome than knee protheses fixated without bone cement. The key to optimize the interfacial strength is achieving and maintaining maximal infiltration of cement into the bone to obtain large inter-digitation and a large contact area. To improve the cement penetration and distribution into the proximal tibia in a cadaver model.

It is hypothesized that cementation in the proximal tibia after a TKA with the new cementing compression device is better compared to the best cementing technique at the moment (finger packing) regarding cement distribution and cement penetration in vivo.

### Doel van het onderzoek

It is hypothesized that the new cement compression device leads to better cement distribution and penetration compared to the current technique (finger packing). It is also hypothesized that there will be less cement leakage and that the duration of surgery is shorter.

### Onderzoeksopzet

2

### Onderzoeksproduct en/of interventie

The use of the cement compression device during cementation of a total knee arthroplasty.

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

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

- Non-inflammatory degenerative joint disease (NIDJD), e.g. osteoarthritis, avascular necrosis;
- Traumatic arthritis;
- The need for a tibia component size 4, 5 or 6 (NexGen Legacy, Zimmerbiomet) during surgery.

Patients must additionally meet all of the following criteria:
- Age > 18 years;
- Patient is willing to participate;
- Patient is able to speak and write Dutch;
- Patient qualifies for TKP based on medical history and physical examination;
- Patient is able and willing to provide written informed consent.

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

- Rheumatoid arthritis or other forms of inflammatory disease(s);
- Uncooperative patient or patient with neurologic disorders who are incapable of following directions;
- Insufficient bone stock to provide adequate support and/or fixation to the prothesis;
- Metabolic disorders which may impair bone formation;
- Osteomalacia;
- Charcot's disease;
- Previous knee surgery exept arthroscopy.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | Geneesmiddel |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-10-2019 |
| Aantal proefpersonen: | 34 |
| Type: | Werkelijke startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 23-10-2019 |
| 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 | NL8109 |
| Ander register | METC LDD : METC Z19.035 |

# Resultaten