# A Cement Compression Device for Cemented TKA

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25335

**Source**
NTR

**Brief title**
CCD-TKA

**Health condition**

Knee osteoarthritis, knee wear

### Sponsors and support

**Primary sponsor:** Vakgroep Orthopedie RdG
**Source(s) of monetary or material Support:** Vakgroep Orthopedie RdG

### Intervention

### Outcome measures

**Primary outcome**

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

**Secondary outcome**

The secondary parameter is the measured operation time.

# Study description

### Background summary

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.

### Study objective

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.

### Study design

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### Intervention

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

# Contacts

**Public**
Reinier de Graaf Gasthuis
Nina Mathijssen

+31 (0) 15 260 3718
**Scientific**
Reinier de Graaf Gasthuis
Nina Mathijssen

+31 (0) 15 260 3718

# Eligibility criteria

## Inclusion criteria

- 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.

## Exclusion criteria

- 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.

# Study design

## Design

Study type: Interventional

| | |
|---|---|
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-10-2019 |
| Enrollment: | 34 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 23-10-2019 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL8109 |

| Register | ID |
| --- | --- |
| Other | METC LDD : METC Z19.035 |

# Study results