# Is there difference of the pre operative planning of the total knee arthroplasty between orthopedic surgeons?

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We hypothesise that there would be no significant difference between the preoperative planning between different orthopedic surgeons.

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

## Samenvatting

### ID

NL-OMON19968

**Bron**
NTR

**Verkorte titel**
TKA

**Aandoening**

This case control study will review a cohort (n= 899 cases) of patients operated for unilateral total knee arthroplasty (TKA) with the use of patient specific matched instruments (PSMI; Signature, Biomet, Warsaw INC).

### Ondersteuning

**Primaire sponsor:** Orthopedie Orbis MC, Sittard-Geleen, the Netherlands
**Overige ondersteuning:** Orthopedie Orbis MC, Sittard-Geleen, the Netherlands

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Changes to the plan, the surgeon can modify the settings for femur and tibia alignment.

# Toelichting onderzoek

### Achtergrond van het onderzoek

To our knowledge, no studies have yet been conducted comparing the pre-operative planning of patients between orthopedic surgeons, experienced with patient specific matched instruments.
This study is designed to address the following research question: is there a significant difference between the alignment of the individual femoral and tibial components as planned.

### Doel van het onderzoek

We hypothesise that there would be no significant difference between the preoperative planning between different orthopedic surgeons.

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

Fifty cases will be random selected from the total cohort. The planning of these cases will be evaluated by 10 international orthopedic surgeons experienced with patient matched instruments. No patients are involved, only the pre operative plan of patients will be used.

Based on 50 plans for each surgeon, inter observer variability will be calculated

Twenty five cases will be random selected from the total cohort. The planning of these cases will be evaluated by 4 orthopedic surgeons. Each case will be planned for 3 times by each surgeon. Surgeons in Orbis Medisch Centrum will participate in this study. No patients are involved, only the pre operative plan of operated patients will be used.

Based on 3 plans for each case, intra-observer variability will be calculated

Based on 25 plans for each surgeon, inter observer variability will be calculated

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

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

Pre operative planned TKA of patients with PSMI

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

N/A

# Onderzoeksopzet

## Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

| | |
|---|---|
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Enkelblind |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-09-2013 |
| Aantal proefpersonen: | 75 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 19-08-2013 |
| 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 | NL3968 |
| NTR-old | NTR4127 |
| Ander register | METC Atrium-Orbis-Zuyd : 13N107 and 13N108 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A