

# Comparison Of Posterolateral and direct Anterior approach in uncemented total hip arthroplasty: treatment outcome and cost-effectiveness

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28364

### Source

NTR

### Brief title

COPA study

### Health condition

Direct anterior approach, DAA, cost-effectiveness, posterolateral, total hip arthroplasty, THA, minimal invasive, Heuter

## Sponsors and support

**Primary sponsor:** Medisch centrum Alkmaar

**Source(s) of monetary or material Support:** Foreest Medical school

## Intervention

## Outcome measures

### Primary outcome

- Hip pain and symptoms assessed using the symptoms, pain and activities of daily living (ADL) subscales of the Hip Dysfunction and Osteoarthritis Outcome Score (HOOS) after three months
- Perceived pain in the week before the moment of assessment, assessed using a Visual Analogue Scale (VAS) after three months

## **Secondary outcome**

- Hip pain and symptoms assessed using the sports & recreation and quality of life subscales of the Hip Dysfunction and Osteoarthritis Outcome Score (HOOS)
- Length of hospital stay
- Quality of life assessed using the EQ-5D
- Functioning during daily living assessed using the HOOS
- Quality of walking assessed during a timed up and go test and a two times 50m walk using inertial sensors
- Operation time, blood loss, and other parameters of the surgical procedures
- Cup and stem positioning assessed using standard radiography
- Cost-Effectiveness assessed using the cost-questionnaire
- Muscle status assessed using MRI in a sample of 15 patients from each group
- Positioning of the implant assessed using CT scans in a sample of 15 patients from each group.
- All complications related to the surgery and rehabilitation
- Productivity costs
- Direct medical costs (costs of additional radiography, medical consumption)

## **Study description**

### **Study design**

Follow up visit at 6 weeks and 12 months

questionnaires at 6 weeks 3 6 9 12 and 24 months

## **Intervention**

Posterolateral approach total hip arthroplasty versus direct anterior THA

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

- ☐ Willing and able to participate in the study protocol;
- ☐ Age between 18 and 80 years
- ☐ ASA Physical Status I & II
- ☐ Diagnosed with osteoarthritis of the hip
- ☐ Subjects for who it is decided that they will undergo an uncemented THA at Medical Centre Alkmaar.

□ Subjects who are able to give voluntary, written informed consent to participate in this clinical investigation and from whom consent has been obtained.

□ Subjects, who, in the opinion of the Clinical Investigator, are able to understand this clinical investigation, cooperate with the investigational procedures and are willing to return for all the required post-treatment follow-ups.

## Exclusion criteria

□ Patients with previous surgery to the ipsilateral or contralateral hip;

□ Patients with posttraumatic changes of the pelvis or femur;

□ Patients with inflammatory arthropathies;

□ Patients diagnosed with osteoporosis

□ Patients diagnosed with rheumatoid arthritis

□ Patients who suffer from insulin dependant diabetes

□ Patients who lack understanding of the Dutch language

□ Patients who are treated for or diagnosed with neurological or muscle disorders which make assessment of pain and gait not possible

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending

Start date (anticipated):	01-03-2015
Enrollment:	172
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	10-03-2015
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 NL4814

NTR-old NTR5086

Other De Medisch Ethische Toetsingscommissie (METC) Noord-Holland :  
MedischcentrumAlkmaar

## Study results