

# Gaitanalyses after resurfacing versus total Metal on Metal hip arthroplasty. An exploratory study

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Primary objective: Is there a difference in gait pattern between patients with a resurfacing hip arthroplasty compared to a total hip arthroplasty after 5 years?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42032

### Source

ToetsingOnline

### Brief title

Gaitanalysis after RHA vs MoM THA

### Condition

- Other condition
- Joint disorders

### Synonym

Gaitanalysis after Hip prosthesis

### Health condition

Loop patroon analyse na heupprothesie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Rijnstate Ziekenhuis

**Source(s) of monetary or material Support:** Stichting vriendenfonds Rijnstate Ziekenhuis

## Intervention

**Keyword:** Gaitanalysis, PROMs, Resurfacing hip arthroplasty, Total Hip Arthroplasty

## Outcome measures

### Primary outcome

primary objective:

The principal objective is to assess top walking speed in patients who have undergone either hip resurfacing arthroplasty or total hip arthroplasty as part of a randomised controlled trial.

### Secondary outcome

Secondary objective:

1. The following will also be assessed to determine if there is a difference between patients after resurfacing or total hip arthroplasty: Top walking incline, ability to run, cadence and stride length.
2. Patient-reported outcome measures: Harris Hip Score (HHS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), EuroQol 5D (EQ-5D), The University of California at Los Angeles (UCLA) activity score will be assessed to establish patient-reported quality of life after surgery.

## Study description

### Background summary

Total hip replacement surgery is a very successful operation with good

long-term results. Hip resurfacing arthroplasty is offered as a treatment option for young and active patients with osteoarthritis of the hip. It has been proposed as a treatment option for younger patients because of claims that it preserves femoral bone stock and has better functional outcomes. The assessment of gait after hip replacement surgery may be able to determine functional differences between patients who have undergone total hip replacement/arthroplasty (THA) versus hip resurfacing.

### **Study objective**

Primary objective: Is there a difference in gait pattern between patients with a resurfacing hip arthroplasty compared to a total hip arthroplasty after 5 years?

### **Study design**

This will be a cross sectional/exploratory study. All patients, part of a randomized controlled trial, will be asked to undergo a gait analysis on a treadmill at 5 years follow up.

### **Study burden and risks**

-There are no clear benefits associated with participation, except for a better understanding of patterns of movement after a hip arthroplasty.

-There are no clear risks associated with participation. Patients will be asked to walk on a treadmill, this will take 15 -20 minutes and they will be asked to walk only as hard as they feel safe to. When feeling discomfort or pain patients can stop at any time their gait analysis. The treadmill is provided with all safety measurements: safety stop button, a safety drawstring and armrests.

## **Contacts**

### **Public**

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NL

### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- 1: Patient part of randomised controlled trial (RCT) of hip resurfacing versus MoM total hip arthroplasty for symptomatic osteoarthritis of the hip versus total hip arthroplasty
- 2: Patient must be able to consent to the study (written informed consent)
- 3: Patients who are functioning well post-operatively and not under routine follow up
- 4: Patients who are able to walk without any safety rail assistance on the treadmill

### Exclusion criteria

- 1: Patient not originally randomised during an RCT of hip resurfacing versus MoM total hip arthroplasty.
- 2: Patients who suffer from any neurological or musculoskeletal conditions that might make a gait test dangerous.
- 3: Patients whose cognitive function prevents them from understanding the study.
- 4: Patients who have had or are awaiting revision surgery for their hip

## Study design

### Design

**Study type:** Observational non invasive

Masking: Single blinded (masking used)

Control: Uncontrolled

Primary purpose: Other

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 24-04-2015  
Enrollment: 58  
Type: Actual

## Ethics review

Approved WMO  
Date: 16-02-2015  
Application type: First submission  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## 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
CCMO	NL50830.091.14