

# Pilot study into the biomechanical working mechanisms of a brace that aims to prevent hip dislocation after total hip replacement surgery

Published: 08-12-2017

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What is the influence of the Rebound Hip and Newport 4 hip brace on restricting the movements that are associated with hip dislocation after at total hip replacement.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | Joint disorders            |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON44352

### Source

ToetsingOnline

### Brief title

Pilot study into brace preventing hip dislocation

### Condition

- Joint disorders

### Synonym

brace preventing hip displacement, Brace preventing hip luxation

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Revalidatiecentrum Het Roessingh

**Source(s) of monetary or material Support:** Ongesubsidieerd

## Intervention

**Keyword:** Biomechanics, Brace, Hip displacement, Total hip arthroplasty

## Outcome measures

### Primary outcome

Peak hip flexion, adduction and rotation angles during the execution of the different tasks.

### Secondary outcome

Peak joint angles of the other joints of the lower extremities.

## Study description

### Background summary

Preventing hip dislocation is an important part of the postoperative care after total hip replacement. Hip dislocation is associated with implant failure and it may lead to recurrent hip dislocations. One of the possible interventions to prevent hip dislocation is the prescription of a brace, such as the Rebound Hip brace, that restricts the movements that are associated with hip dislocations. While these braces are prescribed in daily care there is little scientific knowledge about the efficacy of these braces in preventing risky movements.

### Study objective

What is the influence of the Rebound Hip and Newport 4 hip brace on restricting the movements that are associated with hip dislocation after at total hip replacement.

### Study design

Randomized cross-over trial.

### Study burden and risks

The burden on the subjects is mainly investing a (part of the) day to perform the measurements. Subjects will stand for about a half hour to an hour to apply all measurement equipment after which the measurements will start. The risk of

the measurements is low, as we will study activities that are routinely carried out in daily living.

## Contacts

### **Public**

Roessingh Research and Development

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### **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

- Aged between 40 and 70
- No musculoskeletal problems influencing walking ability and normal range of motion of the hip.
- Be able to be physically (low-intensity) active for a period of 4 hours.

## Exclusion criteria

- Had a joint replacement surgery of one of the joints of the lower extremities.
- Not able to understand Dutch or English instructions.

## Study design

### Design

|                     |                            |
|---------------------|----------------------------|
| Study type:         | Observational non invasive |
| Intervention model: | Crossover                  |
| Masking:            | Open (masking not used)    |
| Control:            | Uncontrolled               |
| Primary purpose:    | Treatment                  |

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 28-05-2018          |
| Enrollment:               | 10                  |
| Type:                     | Actual              |

### Medical products/devices used

|               |  |
|---------------|--|
| Generic name: | Rebound Hip brace; Newport 4 hip brace |
| Registration: | Yes - CE intended use                  |

## Ethics review

|                    |                        |
|--------------------|------------------------|
| Approved WMO       |                        |
| Date:              | 08-12-2017             |
| Application type:  | First submission       |
| Review commission: | METC Twente (Enschede) |

## Study registrations

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

No registrations found.

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

ID: 29467

Source: Nationaal Trial Register

Title:

### In other registers

| Register | ID              |
|----------|-----------------|
| CCMO     | NL63397.044.17  |
| Other    | Nog niet bekend |
| OMON     | NL-OMON29467    |