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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	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

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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