The need for supine position advise in the first period (first 8 weeks) after a total hip replacement to prevent hip dislocation of the hip replacement.

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The primary objective of this study is the to prove that there is no difference in hip dislocation percentage to 8 weeks after total hip replacement in patient with or without the precepts of supine position when lying, in the first 8 weeks after...

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

Summary

ID

NL-OMON45169

Source
ToetsingOnline

Brief title
supine position after total hip replacement

Condition

- Joint disorders

Synonym
arthosis of the hip, coxarthosis

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente

Source(s) of monetary or material Support: eigen financiele middelen

Intervention

Keyword: hip dislocation, precepts, suspine position, total hip replacement

Outcome measures

Primary outcome

The primary study parameters is the number of hip dislocation in the study population.

Secondary outcome

The secondary study parameters are the quality of sleep, the level of functional recovery, adherence, pain and client satisfaction assed by questionnaires.

Study description

Background summary

In 2012, 592 primary total hip replacement were performed by the Orhopedisch Centrum Oost Nederland. In the Netherlands 31.840 primary total hip replacement are placed in 2009. One of the complications after a total hip replacement is hip dislocation. Especially, in the first 8 weeks after the surgery there is a risk for this complication. To reduces this risk patients receive during these 8 weeks precepts. In the Netherlands there is no consensus about these precepts and the Nederlandse Orthopedische Vereniging (NOV) gives no advices. One of these precepts is the supine position for 8 weeks after the surgery. It appears that this precepts is experienced by patients as very stressful and the adherence to this precepts decreases over time (Tijink, 2012).
For the replacement of a hip the OCON uses the posterolateral approach. No literature is known about the added value of precepts after a total hip replacement. However, for the anterolateral approach Peak et al., 2005 conducted a randomized clinical trial to precepts after surgery. The percentage of hip dislocation in the total cohort was less than 1%. There were no difference between with or without precepts concerning supine position. Concerning the low risk of hip dislocation, the diversity of national advises for precepts after surgery, the decrease of adherence over time and the burden

on the patient for supine position during sleep the OCON doubts the added value of the precepts supine position after a total hip replacement.

Study objective

The primary objective of this study is the to prove that there is no difference in hip dislocation percentage to 8 weeks after total hip replacement in patient with or without the precepts of supine position when lying, in the first 8 weeks after surgery.

Study design

A blocked stratified surgeon blinded randomized clinical trial.

Intervention

patients in the intervention group will be exempted from sleeping on the back during the first 8 weeks after total hip replacement surgery. The remaining anti-luxation instructions (for example, bend forward) remain applicable.

Study burden and risks

This study is based on the hypothesis that there is no difference in percentage of hip dislocations between groups with and without supine position as precept. Participants are not burden with extra visits to the clinic. However, participants are asked to fill out questionnaires pre-operative, 8 weeks post-operative and 6 months post-operative. For the patient of the intervention group there is the advantage of no precept concerning supine position during the first 8 weeks after surgery.

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

1. Placement of a primary total hip replacement via the posterolateral approach by hip orthopedic surgeons (Dr. Pakvis, Dr. Rompen Dr. Peters, Dr. Schuppers, Dr. van Doorn, dr. de Windt, dr. Buchholz, dr. Bergink, dr. Homan, dr. Oemar, dr. Wagenaar).
2. Patients with a ASA-classificatie of I or II.

Exclusion criteria

1. Blindness
2. replacement of 2nd total hip within six months after the 1st total hip replacement surgery
3. Insuffcient knowlegde of the Dutch language
4. Collumfracture
5. Infection of total hip replacement
6. Cognitive dysfunction
7. Already dependible of wheelchair
8. Hypermobility
9. Alcohol abuse
10. neurological disorders such as Parkinson and stroke

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2014
Enrollment:	456
Type:	Actual

Ethics review

Approved WMO Date:	25-02-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-02-2016
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL46706.044.13

Study results

Date completed:	26-11-2018
Actual enrolment:	456