The effect of a compression bandage on swelling of the leg after primary THA by ASI approach, a Randomized Controlled Trial.

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Determining differences in postoperative swelling of the leg by the use of postoperative compression bandage of the leg versus a control group with no bandage at all, after primary THA by ASI approach. The length of hospital stay and the occurrence...

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

Summary

ID

NL-OMON40240

Source
ToetsingOnline

Brief title
Effect of compression bandage on swelling of the leg after primary THA.

Condition

- Joint disorders

Synonym
Swelling

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: maatschap orthopedie

Intervention

Keyword: Hiparthroplasty, Leg, Swelling

Outcome measures

Primary outcome

Postoperative swelling of the upper and lower leg measured at multiple moments:

before and immediately after mobilization during hospitalization, and at 7 and

14 days after surgery on the outpatient clinic. Mobilization occurs 6 hours

after surgery and from the first day postoperative twice a day until discharge.

Swelling of the leg is defined as the difference in circumference of the leg in

centimeters, compared to the preoperative circumference of the leg, measured at

2 standardized points.

Length of hospital stay.

Secondary outcome

Occurrence and amount of wound leakage.

Occurrence of wound infection.

Study description

Background summary

In Reinier de Graaf Groep (RdGG) the Anterior Supine Intermuscular technique (ASI) is used for total hip arthroplasty (THA) procedures. This technique will allow the patient to mobilize much earlier postoperatively compared to other techniques. Postoperative swelling of the leg could hinder this early postoperative mobilization. Therefore, this study will investigate the effect of compression bandage on the postoperative swelling of the leg after primary

THA by ASI technique.

Study objective

Determining differences in postoperative swelling of the leg by the use of postoperative compression bandage of the leg versus a control group with no bandage at all, after primary THA by ASI approach. The length of hospital stay and the occurrence and amount of wound leakage and the occurrence of wound infection will be measured also.

Study design

This study is a randomized, controlled trial comparing the outcome in one group of interest, the total hip arthroplasty group, using postoperative compression bandage of the leg versus a control group with no bandage at all.

Patients with osteoarthritis of the hip, who qualify for a primary THA by ASI approach, will be randomized into 2 groups. Group 1 will be given a compression bandage for 24 hours. Group 2 (control group) will be given no bandage at all.

Intervention

not applicable

Study burden and risks

Patients will receive their planned THA. There will be some extra clinical control moments to measure the circumference of the leg. This will be immediately after mobilization, at 4-6 h after surgery and from day 1 postoperatively twice a day until discharge, and at the standard control moment 14 days after surgery.

There will be 1 extra control moment after discharge when compared to normal THA patients. This will be 7 days after surgery for measuring the circumference of the leg as well.

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

Patients diagnosed for THA by ASI approach for osteoarthritis.
Aged 18 and older.

Exclusion criteria

Mentally retarded.
BMI > 35
Participating in another study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-05-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-04-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL44038.098.13