

Spinal or hemi-spinal anesthesia in fast-track total hip arthroplasty and total knee arthroplasty (THA and TKA), a prospective randomized controlled study in the Martini Hospital

Published: 29-09-2014

Last updated: 21-04-2024

Our objective is to answer the question: *Is hemi-spinal anesthesia more effective than spinal anesthesia for THA and TKA in fast track surgery*

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40716

Source

ToetsingOnline

Brief title

Rapid Study

Condition

- Other condition

Synonym

spinal anesthesia versus hemi-spinal anesthesia

Health condition

anesthesie technieken bij orthopedische patienten

Research involving

Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis

Source(s) of monetary or material Support: geen vergoeding beschikbaar

Intervention

Keyword: Fast-track, Spinal versus Hemi-spinal prospective

Outcome measures

Primary outcome

The main endpoint is conversion to general anesthesia which is a measure for effectiveness of (hemi-)spinal anesthesia.

Secondary outcome

Secondary outcomes are length of stay in the post anesthesia care unit (PACU), need for urinary catheterization, intra operative blood loss, motoric dysfunction, postoperative pain and opioid consumption, orthostatic intolerance and dizziness, postoperative nausea and vomiting, reduction in length of stay (LOS)

Study description

Background summary

Spinal anesthesia and hemi-spinal anesthesia are two common anesthesia methods in total hip arthroplasty (THA) or total knee arthroplasty (TKA). The aim of this study is to evaluate whether spinal anesthesia or hemi-spinal anesthesia would provide better perioperative anesthesia, less postoperative side effects, less motoric dysfunction, adequate postoperative pain relief and less orthostatic intolerance in fast-track surgery.

Study objective

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Our objective is to answer the question: *Is hemi-spinal anesthesia more effective than spinal anesthesia for THA and TKA in fast track surgery*

Study design

Study design: A prospective randomized controlled trial design

Study burden and risks

Since both the spinal and hemi-spinal anesthesia are standard approaches for THA and TKA, the additional risks are equal for both groups in the study. Possible benefits for the group of patients undergoing hemi spinal-anesthesia could be better treatment outcomes with respect to the endpoints mentioned above.

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

primary TKA or THA
patients older than 18 year

Exclusion criteria

not a primary THA or TKA
patients with a strong preference for one or the two anesthesia methods
patient who want general anesthesia
patient with a contra-indication for spinal anesthesia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2014
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2014
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO	
Date:	08-10-2015
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL49442.099.14
Other	volgt