Median Local Anaesthetic dose (MLAD) of Intrathecal Bupivacaine in anterior supine intermuscular total hip arthroplasty

Published: 20-07-2015
Last updated: 19-04-2024

The objective of this study is to find the median local anesthetic dose (MLAD/ED50) of bupivacaine that allow direct post-operative mobilization and will accommodate sufficient anesthesia during surgery.Results from this study might lead to the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON43572

Source
ToetsingOnline

Brief title
ED50 of Intrathecal Bupivacaine in Total Hip Arthroplasty

Condition

- Bone and joint therapeutic procedures

Synonym
Anesthesia

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Vakgroep orthopedie RdGG

Intervention

Keyword: anterior supine inter muscular approach, Intrathecal anaesthesia, Median effective dose, Total hip arthroplasty

Outcome measures

Primary outcome

MLAD/ED50 of bupivacaine at t-119 minutes

Secondary outcome

not applicable

Study description

Background summary

Total hip arthroplasty (THA) has become a common elective orthopedic procedure surgical orthopedic procedure. Surgical approaches for THA have evolved over the years leading to lees postoperative pain and reduction of length of stay. Moreover, the peri-operative management has developed in order to improve outcomes. As a result fast track programs have evolved as a multimodal procedure to achieve faster rehabilitation, reduction of organ dysfunction, morbidity and mortality. In fast-track total hip arthroplasty, spinal anesthesia with bupivacaine is preferred over general anesthesia due to less nausea, vomitting and less blood loss.

Mean surgery time for Total Hip arthroplasty with the anterior supine intermuscular approach at RdGG is 69,7 minutes and other studies found a mean surgery time of 68,5 minutes. Provided that administration of 8mg of bupivacaine intrathecal at level L3-L4 will lead to a motor block of 100-225 minutes according to Gautier et al. it might be possible to reduce the amount of bupivacaine used during surgery in order to optimize rehabilitation after THA.

Current dosages of thecal bupivacaine are adequate for allowing surgery with total analgesia but do not provide optimization for direct post-operation mobilization and often leave patients unable to mobilize for several hours post-surgery prolonging a patients hospital stay.

Study objective

The objective of this study is to find the median local anesthetic dose (MLAD/ED50) of bupivacaine that allow direct post-operative mobilization and will accommodate sufficient anesthesia during surgery.

Results from this study might lead to the justification of lower doses of bupivacaine used for anesthesia in THA. Henceforth, the fast track program can be optimized and rehabilitation can start immediate postoperatively.

Study design

This is an intervention study designed to find the MLAD/ED50 of bupivacaine at a certain threshold.

In this study we use the up-and-down method as described by Dixon and Massey. This is a sequential allocation model where patients receive a dose of bupivacaine according to the outcome of the preceding patient. With the up and down method we approach the MLAD/ED50 from above leaving less patients with inadequate anesthesia. For the cut-off point or threshhold point needed with this model we use the 95th percentile of the mean surgery time for THA-ASI in order to expose less patients to inadequate anesthesia during surgery.

At the cut-off point patients must be able to fully recover from the sensory- and motor blockade induced by bupivacaine. Therefore, at the cut-off point (119 minutes after spinal anesthesia is administered) patients much reach;

- Full recovery of the motor block, measured with the modified bromide scale (Bromage 0)
- Full recovery of the sensory block (positive pinprick test at the S1 and L5 Dermatome)

Possible test outcomes;
1. Patient reach the cut-off parameters before 119 minutes -> inadequate bupivacaine
2. patient reach the cut-off parameters after 119 minutes -> adequate bupivacaine
If a patient is documented with inadequate anesthesia (possible outcome 1) the succeeding patient receives a dose of bupivacaine Xy+0,5mg
If a patient is documented with adequate anesthesia (possible outcome 2) the succeeding patient receives a dose of bupivacaine Xy-0,5mg

During surgery sensory block height is assesed using a pinprick test. The patient is asked to score pain on the NRS for pain. Testing will be perfomed in 10 minute intervals starting from the injection of bupivacaine.
After surgery sensory block recovery is assesed using a pinprick test at

dermatome L5 and S1. Suplementery recovery from motor block is assed by assesing the modiefied bromage scale. After surgery the testing will be performed in 10 minute intervals until the cut-off parameters are reached.

Intervention

The patients will undergo surgery according to the THA-ASI protocol. The intervention targets the spinal anesthesia protocol. The current protocol imposes a dose of 8mg of Bupivacaine administered intrathecally at the L3-L4 intervertebral space. In this study we lower the dose for the succeeding patient according to the outcome of the preceding patient.

The patient will undergo testing and monitoring in 10 minute intervals starting from the start of injection up until it*s recovery from the nerve blockade.

Study burden and risks

Patients will receive their scheduled THA according to the regular planned fast track surgery programme. The up-and-down sequential allocation technique, rather than random allocation, is chosen due to the ease with which it estimates the mean of a sample. By starting from known effective concentration and approaching the ED50 from above, the number of patients subjected to potentially inadequate analgesia is minimized.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- ASA I to III
- 18y or older
- Primary uncemented THA-ASI
- Willing to participate
- Speaking Dutch language

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Hypersensitivity to local anesthetics or any of the other excipients of Bupivacaine
- Any other contraindications relate to intrathecal anesthesia
- CNS disease, e.g. meningitis, tumor, poliomyelitis, cerebral haemorrhage
- Spinal stenosis and diseases or recent trauma to the cervical column
- Sepsis
- Pernicious anemia with symptoms related to cervical degradation
- Pyogenic infections of the skin close to the injection site
- Cardiogenic or hypovolemic shock
- Disturbance in coagulation or treatment with anti-coagulants
- Patient is participating in a medicinal study
- Noncompliant to intrathecal anesthsia
- Patients who are incompetent to decide

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2015
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Marcaine 5mg/ml spinaal
Generic name:	bupivacaïnehydrochloride
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	20-07-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-09-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-02-2016
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
EudraCT	EUCTR2015-002958-12-NL
CCMO	NL54186.098.15