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Spinal morphine for postoperative analgesia - safety and effectiveness depending on doses

Submission date
13/04/2022

Recruitment status
No longer recruiting

Registration date
20/04/2022

Overall study status
Completed

Last Edited
06/12/2022

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Total hip arthroplasty is a high-demand surgical procedure in which the damaged hip joint is replaced by a prosthetic implant. After surgery pain can adversely affect the recovery of patients and their early rehabilitation. Therefore it is very important to reduce pain with minimal complications. Spinal anaesthesia is a gold standard for hip replacement. Adding low-dose morphine to intrathecal bupivacaine could prolong analgesia and reduce pain. The aim of this study is to reduce acute pain in patients after total hip arthroplasty using low-dose morphine and to measure the side effects of morphine.

Who can participate?
Patients aged 18-80 years scheduled to have a total hip replacement with spinal anaesthesia

What does the study involve?
Participants are randomly allocated into three study groups. Before surgery group I receive spinal anaesthesia with bupivacaine 15-18 mg, group II receive spinal anaesthesia with 0.1 mg morphine and bupivacaine 15-18 mg, and group III receive spinal anaesthesia with 0.2 mg morphine and bupivacaine 15-18 mg All patients receive standardized analgesia in the postoperative period and are asked about their pain at 4, 7, 12 and 24 hours. Frequency of breathing, oxygen levels, morphine consumption, need for additional oxygen inhalation, and adverse reactions (nausea, vomiting, itching, etc) are all recorded.

What are the possible benefits and risks of participating?
Benefits for participants include having a postoperative period with high control and attention from staff and regular visits from nurses and doctors, and suspected lower levels of pain for the experimental groups. Risks of participating include adverse reactions after morphine (shortness of breath, nausea, vomiting, itching etc).

Where is the study run from?
Hospital of Traumatology and Orthopaedics (Latvia)

When is the study starting and how long is it expected to run for?
February 2020 to May 2021

Who is funding the study?
Hospital of Traumatology and Orthopaedics (Latvia)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
24/2020/1

Study information

Scientific Title
Safety and effectiveness of different spinal morphine doses for postoperative analgesia after primary hip replacement

Acronym
SMPA

Study objectives
The most effective dose of intrathecal morphine is 0.2 mg, it will provide the best analgesic effect without any significant adverse reactions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/05/2020, TOS Hospital of Traumatology and Orthopaedics Ethics Committee (Latvia, Riga, Duntes Street 22, Latvia; +371 (0)29 212 691; marika.ziedina@tos.lv), ref: 24/2020

Study design
Single-centre interventional single-blind prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Outcomes after different spinal morphine doses for patients undergoing hip replacement surgery

Interventions
Using https://www.randomizer.org/ patients are divided into three study groups.

Before surgery:
Group I receive spinal anaesthesia with Sol. Bupivacaine 15-18 mg
Group II receive spinal anaesthesia with 0.1 mg morphine + Sol. Bupivacaine 15-18 mg
Group III receive spinal anaesthesia with 0.2 mg morphine + Sol. Bupivacaine 15-18 mg

All patients receive standardized multimodal analgesia in the postoperative period with etoricoxib, acetaminophen and dexamethasone, rescue medication is morphine 10 mg s/c if the pain is more than 5 by NRS.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bupivacaine, morphine, etoricoxib, acetaminophen, dexamethasone

Primary outcome(s)
1. Pain measured using the numeric rate scale (NRS) at baseline, 4, 7, 12, and 24 hours
2. Respiratory rate (x/min) measured using a vital sign monitor in the postoperative recovery room at baseline, 4, 7, 12, and 24 hours
3. Arterial blood oxygen saturation (SpO_2,%) measured using a vital sign monitor in the postoperative recovery room at baseline, 4, 7, 12, and 24 hours

Key secondary outcome(s))
1. Morphine 10 mg s/c is injected by a nurse on patient request if pain is more than 5 points (by NRS), each injected dose is noted by a nurse in the narcotic drug copy-book and consumption is

counted in 24 h by the researcher and noted in the research protocol
2. Additional oxygen consumption: time (min) and speed (l/min) of additional oxygen supply. The period of time when the patient has inhaled additional oxygen and the speed (l/min) of the supply is noted in the patient observation form by a nurse and in the research protocol by the researcher.
3. The incidence of any adverse reactions (nausea, vomiting, itching, urine retention) measured using a formula (incidence = cases/total number of patients in the research group). The case of each adverse reaction is noted by a nurse in the patient observation form during 48 h after surgery.

Completion date
02/05/2021

Eligibility

Key inclusion criteria
1. Patient is scheduled for total hip replacement under spinal anaesthesia
2. Aged 18-80 years
3. Body mass index (BMI) <35 kg/m²
4. ASA Physical Status Classification System < IV

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
90

Key exclusion criteria
1. Patient rejection
2. Drug allergy to medications included in this study
3. Severe respiratory disorders
4. BMI >35 kg/m²
5. Patient is not able to understand the main points of the research
6. Patient is enrolled in another clinical trial

Date of first enrolment
01/06/2020

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
Latvia

Study participating centre
The Hospital of Traumatology and Orthopaedics (TOS)
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Sponsor information

Organisation
University of Latvia

ROR
https://ror.org/05g3mes96

Organisation
Hospital of Traumatology and Orthopaedics

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital of Traumatology and Orthopaedics

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study are available upon request from Eva Vītola (evavitola2@gmail.com). Data will be sent by email in PDF format in the Latvian language (during the study data were registered on a paper format document in the Latvian language). Data will be sent by email upon request or will be published as a supplement to the results publication if necessary. Type of data: Patient Consent Form with signature of patient; personal data of patients; study-related results and measures of each patient. Data will be shared only with the ISRCTN service for trial registration and with the peer-review committee for publication in a peer-reviewed journal.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/12/2022	06/12/2022	Yes	No
Other unpublished results			09/08/2022	No	No
Protocol file			09/08/2022	No	No