

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

Submission date 13/04/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/12/2022	Condition category Surgery	<input type="checkbox"/> 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?
Dr Iveta Golubovska
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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, Dunties 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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 (SpO₂,%) measured using a vital sign monitor in the postoperative recovery room at baseline, 4, 7, 12, and 24 hours

Secondary outcome measures

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.

Overall study start date

01/02/2020

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

96

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

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University/education

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Sponsor type

Hospital/treatment centre

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Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital of Traumatology and Orthopaedics

Results and Publications

Publication and dissemination plan

Planned publication in BMC Anaesthesiology or another high-impact peer-reviewed journal that accepts retrospective registration.

Intention to publish date

31/12/2022

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?
Other unpublished results			09/08/2022	No	No
Protocol file			09/08/2022	No	No
Results article		05/12/2022	06/12/2022	Yes	No