Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation of adding Lidocaine to Morphine in patient controlled analgesia on pain intensity after unilateral knee prosthesis surgery by spinal anesthesia

Protocol summary

Study aim
We measure pain reduction after unilateral knee arthroplasty after adding lidocaine to morphine in a patient controlled analgesia pump.

Design
Clinical trial with a control group, with parallel groups, three blinded, randomized, phase 2-3 on 58 patients.

Settings and conduct
This study was conducted in Aria and Farabi hospitals in Mashhad. A pain pump was placed for the patients for post-operative analgesia. The pain level of the surgical site was compared with the Visual Analogue Scale method at specific time intervals. In this study, drugs were used with the same packaging and blinding was done for patients, project personnel and researchers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with American Society of Anesthesiologists (ASA) class 1 and 2 between 45 and 75 years old, with a Body Mass Index(BMI) in the range of 20-25 should undergo spinal anesthesia for the surgery؛ Exclusion criteria: Patients with a history of epilepsy, known kidney disease, heart block, or drug addiction, Patients with a medical history that indicates hypersensitivity to lidocaine and opioids, Patients with coagulation disorders, Patients with skin infection at the injection site, a history Moderate to severe nausea and vomiting in the past 24 hours

Intervention groups
Group A: The content of the patient controlled analgesia pump attached to the patient included 20 mg of morphine, 8 mg of Ondansetron ampoule (4 cc), 1g of Apotel (6.7 cc) and the rest of normal saline to reach a total volume of 100 cc Group B: The content of the patient controlled analgesia pump includes 10 mg of morphine, 50 cc of lidocaine 2%, 8 mg of ampoule of Ondansetron (4 cc), 1g of Apotel (6.7 cc) and the rest of normal saline to a total volume of 100 cc.

Main outcome variables
Postoperative pain; mean arterial pressure; heart rate; nausea and vomiting; systolic pressure; diastolic pressure

General information

Reason for update
Acronym
PCA
IRCT registration information
IRCT registration number: **IRCT20200718048125N2**
Registration date: **2022-12-14, 1401/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-14, 1401/09/23**
Update count: **0**
Registration date
2022-12-14, 1401/09/23

Registrant information
Name
Hamed Beyzaii
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-27, 1401/09/06
Expected recruitment end date
2023-03-19, 1401/12/28

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of adding Lidocaine to Morphine in patient controlled analgesia on pain intensity after unilateral knee prosthesis surgery by spinal anesthesia

Public title
The effect of adding lidocaine to morphine on pain intensity after unilateral knee prosthesis surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are in American Society of Anesthesiologists(ASA) class 1 and 2 Patients who are between 45 and 75 years old Patients with a Body Mass Index(BMI) in the range of 20-25 Patients who undergo spinal anesthesia for surgery
Exclusion criteria:
Patients with a history of epilepsy Patients with known kidney disease Patients with heart block Patients with drug addiction Patients with medical histories that show sensitivity to lidocaine and opioid substances Patients with coagulation disorders Patients with skin infection at the injection site Patients who had a history of moderate to severe nausea and vomiting in the last 24 hours
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method is used. We assign an A and B code to each anesthetic intervention. With the lottery method, patients will be placed in one of two codes. In this way, 29 codes A and 29 codes B are written on the paper and each paper is placed inside a special non-transparent sealed envelope and the envelopes are randomly placed on top of each other. Upon the entry of each qualified patient, an envelope is returned by the anesthesiologist to that patient and according to the code written on the paper inside, the anesthetic method is applied.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, patients are placed in two separate groups, A and B, which have the same drug composition except for one type of drug, and drugs with the same shape and packaging are injected to the patients through a patient controlled analgesia pump. The patient does not know whether he is in the control group or the intervention group. The personnel cooperating in the plan do not know the content of the pain pump. The researcher also has no knowledge of which group each patient is in and only analyzes the information.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University, Mashhad branch
Street address
No. 8, Emam Khomeini Ave, Shahinfar Medical School
City
Mashhad
Province
Razavi Khorasan
Postal code
9187147578
Approval date
2022-11-16, 1401/08/25
Ethics committee reference number
IR.IAU.MSHD.REC.1401.157

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee
ICD-10 code
M17.9
ICD-10 code description
Osteoarthritis of knee, unspecified

Primary outcomes

1

Description
Postoperative pain
Timepoint

Immediately after the surgery and 4 hours after the surgery, 8 hours after the surgery, 24 hours after the surgery

Method of measurement

Visual Analogue Scale

2

Description

Heart rate

Timepoint

Immediately after the surgery and 4 hours after the surgery, 8 hours after the surgery, 24 hours after the surgery

Method of measurement

Pulse oximetry

3

Description

Mean arterial pressure

Timepoint

Immediately after the surgery and 4 hours after the surgery, 8 hours after the surgery, 24 hours after the surgery

Method of measurement

Clinical examination

4

Description

Postoperative nausea and vomiting

Timepoint

4 hours after the surgery, 8 hours after the surgery, 24 hours after the surgery

Method of measurement

Clinical examination

5

Description

Oxygen saturation

Timepoint

Immediately after the surgery and 4 hours after the surgery, 8 hours after the surgery, 24 hours after the surgery

Method of measurement

Pulse oximetry

6

Description

Systolic pressure

Timepoint

Immediately after the surgery and 4 hours after the surgery, 8 hours after the surgery, 24 hours after the surgery

Method of measurement

Dial sphygmomanometer

7

Description

Diastolic pressure

Timepoint

Immediately after the surgery and 4 hours after the surgery, 8 hours after the surgery, 24 hours after the surgery

Method of measurement

Dial sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Spinal anesthesia; 25-gauge spinal needle (Dr.J Tianjin Hanaco Medical Co. Tianjin, China) was introduced, then 0.5% Bupivacaine mixed with 0.2 mg of Adrenaline was injected at either the third or fourth lumbar epidural space with median or paramedian approach. The content of the patient controlled analgesia pump attached to the patient included 20 mg of morphine, 8 mg of Ondansetron ampoule (4 cc), 1g of Apotel (6.7 cc) and the rest of normal saline to reach a total volume of 100 cc.

Category

Treatment - Drugs

2

Description

Intervention group: Spinal anesthesia; 25-gauge spinal needle (Dr.J Tianjin Hanaco Medical Co. Tianjin, China) was introduced, then 0.5% Bupivacaine mixed with 0.2 mg of Adrenaline was injected at either the third or fourth lumbar epidural space with median or paramedian approach. The contents of the patient controlled analgesia pump include 10 mg of morphine, 50 cc of 2.8% lidocaine, 8 mg of Ondansetron ampoule (4 cc), one gram of Apotel (6.7 cc) and the rest of normal saline to reach a total volume of 100 cc.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Hamed Beyzaee

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2

Recruitment center

Name of recruitment center
Aria hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Tooraj Zandbaf

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Hamed Beyzaee

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available