Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of administration of Ropivacaine-Fentanyl and Ropivacaine-Sufentanil combination on the characteristics of sensory and motor block in lower limb surgery under spinal anesthesia

Protocol summary

Study aim
Comparison of the effects of Fentanyl-Bbupivacaine and Sufentanil-Bbupivacaine

Design
Clinical trial with a control group, with parallel groups, three blinded, randomized, phase 2 on 105 patients. A lottery will be used for randomization.

Settings and conduct
This is a three-blind randomized clinical trial conducted on 105 patients candidate for lower limb surgery under spinal anesthesia in Kashani and Al-Zahra hospitals in Isfahan. After the ethics committee's approval and obtaining the patient's consent, the patients are randomly assigned into groups, the desired intervention is applied in each group, and the patient's clinical symptoms are recorded. The researcher who registers and collects data and the data analyst are not aware of the type of intervention applied. although the patients are included in the study, they are not aware of the type of intervention applied and therefore they are all blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients over 18 years old, candidate for lower limb surgery under spinal anesthesia, ASA anesthesia class I and II, informed consent to participate in the study Non-entry criteria: infection at the injection site, coagulation disorders, high intracranial pressure, drug addiction, and BMI over 30.

Intervention groups
Intervention group A: Patients in this group receive 3 ml of Ropivacaine 0.5% along with 25 micrograms of Fentanyl (0.5 CC from the ampoule) for spinal anesthesia. Intervention group B: Patients in this group receive 3 ml of Ropivacaine 0.5% along with 25 micrograms of Sufentanil (0.5 CC from the ampoule) for spinal anesthesia. Control group C: Patients in this group receive 3 ml of 0.5% Ropivacaine along with 0.5 CC of distilled Water for spinal anesthesia.

Main outcome variables
Time of sensory and motor block effect; the time to reach the maximum sensory and motor block; Duration of sensory and motor block

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20081013001328N2**
Registration date: **2022-09-06, 1401/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-06, 1401/06/15**
Update count: **0**

Registration date
2022-09-06, 1401/06/15

Registrant information

Name
mohammad ali vakili

Name of organization / entity
esfahan medical university

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-10-23, 1401/08/01

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

Scientific title
Comparison of the effect of administration of Ropivacaine-Fentanyl and Ropivacaine-Sufentanil combination on the characteristics of sensory and motor block in lower limb surgery under spinal anesthesia

Public title
Comparison of the effect of Ropivacaine-Fentanyl and Ropivacaine-Sufentanil administration on spinal anesthesia
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years and above Candidate for lower limb surgery under spinal anesthesia ASA class I and II informed consent to enter the study
Exclusion criteria:
Infection at the injection site Coagulation disorders and the use of anticoagulants Suffering from high intracranial pressure Drug addiction Patients with body mass index (BMI) above 30
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
This is a simple randomized clinical trial in which patients enter the study groups by lottery; The medicines and placebo are placed in the sealed, opaque, and similar form packets coded. Each code is also written on a piece of paper, folded, and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box; The pocket with the same number is the intervention that will apply to him. This process continues till the number of patients reaches the desired one.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a three-blind clinical trial; In this way, before obtaining consent, the patients will be included in the study, but they do not know which group they will be in, and therefore they are blind. The researcher who records the patient's symptoms and collects the data related to the outcome variables, and also the person who analyzes the data collected during the study, do not know the type of intervention applied and therefore they are all blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences
Street address
Hezar Jarib St
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2022-02-10, 1400/11/21
Ethics committee reference number
IR.MUI.MED.REC.1400.798

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The time to onset of the numbing
Timepoint
Every 30 seconds from the moment of injection to the first feeling of numbing at the level of the L4 vertebra
Method of measurement
Pinprick and Timer

2

Description
Duration of reaching the maximum level of numbing
Timepoint
Every 30 seconds from the moment of injection to

numbing of the T12 vertebra surface

Method of measurement

Pinprick and Timer

3

Description

Duration of return of numbing

Timepoint

From the time of drug injection until the return of sensation at S1 level

Method of measurement

Pinprick and Timer

Secondary outcomes

1

Description

Blood Pressure

Timepoint

before the injection, 3, 5, and 10 minutes after the spinal and then every 15 minutes until the end of recovery

Method of measurement

Sphymomanmeter

2

Description

Heart Rate

Timepoint

before the injection, 3, 5, and 10 minutes after the spinal and then every 15 minutes until the end of recovery

Method of measurement

ECG monitoring

3

Description

Oxygen Saturation

Timepoint

From the moment of entering the operating room until the end of recovery

Method of measurement

Pulse Oximeter

Intervention groups

1

Description

Intervention group A: Patients in this group are sedated with fentanyl prodrugs at a dose of 1 µg/kg and Midazolam at a dose of 20 µg/kg after monitoring and fluid therapy, and oxygen with a flow of 6-8 liters is established for the patient. Then they receive 3 ml of Ropivacaine 0.5% made by Sinadaro company along with 25 micrograms (equivalent to 0.5cc) of Fentanyl made by Caspin Pharmaceutical Company for spinal anesthesia.

Category

Diagnosis

2

Description

Intervention group B: Patients in this group are sedated with fentanyl prodrugs at a dose of 1 µg/kg and Midazolam at a dose of 20 µg/kg after monitoring and fluid therapy, and oxygen with a flow of 6-8 liters is established for the patient. Then they receive 3 ml of Ropivacaine 0.5% made by Sinadaro company along with 2.5 micrograms (equivalent to 0.5cc) of Sufentanyl made by Caspin Pharmaceutical Company for spinal anesthesia.

Category

Diagnosis

3

Description

Control group C: Patients in this group are sedated with fentanyl prodrugs at a dose of 1 µg/kg and Midazolam at a dose of 20 µg/kg after monitoring and fluid therapy, and oxygen with a flow of 6-8 liters is established for the patient. Then they receive 3 ml of Ropivacaine 0.5% made by Sinadaro company along with 0.5cc of distilled water made by Caspian pharmaceutical company for spinal anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Kamran Montazeri

Street address

Soffeh boulevard, Shahid Keshvari highway

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2

Recruitment center

Name of recruitment center

kashani hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan University of Medical Sciences
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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available