Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effect of low dosage of midazolam plus ketamine and low dose ketamine plus midazolam on postoperative shivering after spinal anesthesia.

Protocol summary

Study aim
Comparison of the prophylactic use of two different doses of Ketamine and Midazolam for prevention of shivering during spinal anesthesia.

Design
The first group receives 0.2 mg/kg of midazolam with ketamine 0.3 mg/kg, the second group receives 0.4 mg/kg of midazolam with low dose ketamine 0.15 mg/kg and the third group receives normal saline. A randomized double-blind clinical trial is conducted on 120 patients undergoing surgery with spinal anesthesia.

Settings and conduct
Patients are referred to al-Zahra hospital. The patients are randomly divided into three groups including those who receive low dose Midazolam with Ketamine (a), Midazolam with low dose Ketamine (b) and Normal saline (c). The Participants, Care provider, Outcome assessor, and Data analyser are not aware of the drug type and the investigator deciphers the codes after data analysis.

Participants/Inclusion and exclusion criteria
Included criteria: 18 to 45 years old; the physical condition of the ASAI-II; undergoing elective surgery under spinal anesthesia Excluded criteria: allergic to the drug; blood transfusion; change the anesthesia method

Intervention groups
They are divided into three groups A, B, and C. The first group midazolam with ketamine, the second group received midazolam dosed with low dose ketamine and a third group received normal saline.

Main outcome variables
shivering

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160307026950N8**
Registration date: **2018-07-27, 1397/05/05**
Registration timing: **retrospective**

Last update: **2018-07-27, 1397/05/05**
Update count: **0**

Registration date
2018-07-27, 1397/05/05

Registrant information

Name
Behzad Nazemroaya

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-06-22, 1396/04/01

Expected recruitment end date
2018-06-22, 1397/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of low dosage of midazolam plus ketamine and low dose ketamine plus midazolam on

postoperative shivering after spinal anesthesia.

Public title
Effects of low dosage of midazolam plus ketamine and low dose ketamine plus midazolam on shivering
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
age 18 to 45 years old Candidate for surgery Anesthesia Technique Spinal Anesthesia ASAI,ASAII
Exclusion criteria:
Change in Anesthesia Technique Bleeding during blood transfiusion Allergy to the drug
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to the 3 groups of A, B, and C using random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
All drugs are prepared and placed at the same volume and homogeneously into the syringes by the investigator. The hemodynamic changes (after the administration of each drug) are monitored and recorded. Moreover, the Participants, Care provider, Outcome assessor, and Data analyser are not aware of the drug type and the investigator deciphers the codes after data analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2017-05-24, 1396/03/03
Ethics committee reference number
ir.mui.rec.1396.3.364

Health conditions studied

1

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

Primary outcomes

1

Description
shivering
Timepoint
Recovery Duration
Method of measurement
In minutes using the timer

2

Description
Temperature of Peripheral
Timepoint
At the base time; after the procedure and then every 15 minutes until discharge of recovery.
Method of measurement
Skin Thermometer

3

Description
Central temperature
Timepoint
At the base time; after the procedure and then every 15 minutes until discharge of recovery.
Method of measurement
Tympanic thermometer

4

Description
Heart Rate
Timepoint
At the base time; after the procedure and then every 15 minutes until discharge of recovery.
Method of measurement
Electrocardiogram

5

Description
Mean Arterial Blood Pressure
Timepoint
At the base time; after the procedure and then every 15 minutes until discharge of recovery.
Method of measurement
Non invasive blood pressure measurement

6

Description
Oxygen saturation
Timepoint
At the base time; after the procedure and then every 15 minutes until discharge of recovery.
Method of measurement
Pulse oximetry device

Secondary outcomes

1

Description
Duration of surgery
Timepoint
The time to start the surgery until the end of the surgery
Method of measurement
Minute

2

Description
Duration of stay in recovery
Timepoint
From admission to recovery until discharge
Method of measurement
Minute

3

Description
Nausea and Vomiting
Timepoint
During stay in recovery
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group B: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulsoximetry, capnography, and electrocardiogram are attached. In this group, low dose Midazolam and Ketamine are injected and subsequent shivering is checked.
Category
Prevention

2

Description
Intervention group C: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulsoximetry, capnography, and electrocardiogram are attached. In this group, low dose midazolam and ketamine are injected and induced shivering in them will be checked. In this group, low dose Ketamine and midazolam are injected and subsequent shivering in them is checked.
Category
Prevention

3

Description
Control group A: Initially, personal consent is obtained from the patients. Then the patient is placed on the operating bed and standard monitoring devices including pulsoximetry, capnography, and electrocardiogram are attached. In this group, low dose Midazolam and Ketamine are injected subsequent shivering in them is checked. In this group, Normal saline is injected and resultant shivering in them is checked. In this group, Normal saline is injected and subsequent shivering in them is checked.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Zahra hospital
Full name of responsible person
Behzad Nazemroaya
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghyegh Haghjoo

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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

Name of organization / entity
Esfahan University of Medical Sciences
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Sara Azizollahi
Position
Medical student/ Intern
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Statistical Analysis Plan
Not applicable

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

Not applicable

Title and more details about the data/document

Only registered symptoms can be published without mentioning the names of the participants

When the data will become available and for how long

Starting the access period 6 months after printing results

To whom data/document is available

Only available to scholars working in academia and academia

Under which criteria data/document could be used

Written request via email and university approval

From where data/document is obtainable

By contacting the corresponding author

What processes are involved for a request to access data/document

After the email is received by the applicant, it takes one week to agree The university will be obtained and then will be notified to the requestor. Maximum of this process takes ten days.

Comments