

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the effect of ketamine as a prevention of shivering after spinal anesthesia in lower limb orthopedic surgery in 5Azar hospital in 1402(2023)

Protocol summary

Study aim

Investigating the effect of ketamine as a prevention of shivering after spinal anesthesia in lower limb orthopedic surgeries.

Design

This clinical trial study has a control group and a control group, a blinded, randomized using block method, phase 3 study on 30 people.

Settings and conduct

The study population is the patients referred to 5 Azar Hospital in Gorgan in 1402 who were hospitalized for orthopedic surgery on the lower limbs. Blinding of the study, random allocation is one-sided and the anesthesia technician will not know the type of drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 60-18 years ASA1. 2 Lower limb orthopedic surgery Normal PT-PTT tests Exit criteria:Contraindications of spinal anesthesia.

Intervention groups

Immediately after spinal anesthesia, 0.25 mg/kg of ketamine and placebo (normal saline) are injected intravenously according to the study group. The information will be charted every 15 minutes according to the checklist.

Main outcome variables

Nausea and vomiting, sedation caused by ketamine and changes in blood pressure and hear rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231002059586N1**

Registration date: **2023-10-23, 1402/08/01**

Registration timing: **prospective**

Last update: **2023-10-23, 1402/08/01**

Update count: **0**

Registration date

2023-10-23, 1402/08/01

Registrant information

Name

Kazem Kazemnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3115 3367

Email address

kazemnejad@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of ketamine as a prevention of shivering after spinal anesthesia in lower limb orthopedic surgery in 5Azar hospital in 1402(2023)

Public title

Evaluation the effect of ketamine as a prevention of shivering after spinal anesthesia in lower limb orthopedic surgery in 5Azar hospital in 1402(2023)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the study subjects is 18-60 years ASA1, 2 Orthopedic surgery of the lower limb PT-PTT tests are normal The patient must consent to the research.

Exclusion criteria:

Patient dissatisfaction with spinal anesthesia ASA 3,4,5 Neurological and psychiatric diseases Myelopathy and peripheral neuropathies Spinal canal stenosis Aortic stenosis Infection High blood pressure is not controlled History of cerebral aneurysms High intracerebral pressure Pregnancy MI in the last 3 months

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

people Participating in this study are randomly assigned to two groups of ketamine and placebo. In this way, using a 6-sided dice, the samples are assigned to their groups. A number is written on each side, and each number is assigned to one of the blocks in the table, which shows the desired drug group. K K P K P 1 P P K P K 2 K K P P K 3 K P P K P 4 P P K P K 5 P K K K P 6

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients are not aware of the type of study group and the selection of the patient, each patient's group and the type of medication received will be delivered by one of the researchers related to the patient. The anesthesiology technician in charge of the patient will not know the type of drug in order to reduce the confounding factors, so according to the two groups of injectable drugs, two types of similar syringes that have no specifications will be used and related medication will be prepared by the anesthesia assistant.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

5 Azar Hospital, 5 Azar Street

City

gorganodhfhk 5

Province

Golestan

Postal code

4917763681

Approval date

2023-07-25, 1402/05/03

Ethics committee reference number

IR.GOUMS.REC.1402.193

Health conditions studied

1

Description of health condition studied

The effect of ketamine in the prevention of shivering after spinal anesthesia.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Shivering

Timepoint

The occurrence of shivering is checked in 15, 30, 45, 60, 75 minutes after the spinal procedure.

Method of measurement

Based on the patient's clinical symptoms of having or not having shivering, it is done.

Secondary outcomes

1

Description

Hemodynamic changes including: Change in mean arterial pressure

Timepoint

It is measured after spinal anesthesia in 15, 30, 45, 60, 75 minutes.

Method of measurement

mmHg, number per minute, percent

2

Description

nausea and vomiting

Timepoint

The occurrence of nausea and vomiting after spinal anesthesia is checked in 15, 30, 45, 60, 75 minutes.

Method of measurement

It is evaluated based on the occurrence of symptoms of nausea and vomiting.

3

Description

Change in heart rate

Timepoint

It is checked based on the rate of heart rate change after spinal anesthesia in 15, 30, 45, 60, 75 minutes.

Method of measurement

It is measured by the number of heartbeats per minute.

4

Description

Hallucination: Misunderstanding of objects or events that involve human senses. Visual hallucinations are more common in the use of ketamine.

Timepoint

It is checked based on the occurrence of hallucination symptoms after spinal anesthesia in 15, 30, 45, 60, 75 minutes.

Method of measurement

Hallucination is evaluated based on having or not having clinical symptoms.

Intervention groups

1

Description

Intervention group: Ketamine injection

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Azar 5 hospital

Full name of responsible person

Kazem Kazemnejad

Street address

Department of Anesthesia, 5 Azar Hospital, 5 Azar St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Pparvaneh Ebrahimzadeh

Position

Anesthesia assistant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Contact

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kazem kazemnejad

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

assistant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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5 Azar Hospital, 5 Azar Street

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Phone

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

The reason for this is due to the observance of ethical principles and the observance of the confidentiality of the patient's personal information.

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The data includes specific variables, and in case of side effects, the related data will be shared.

When the data will become available and for how long

Access will start 6 months after the results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The information can be accessed by observing the ethical principles, maintaining the confidential information of the patients and mentioning the name of the study.

From where data/document is obtainable

Ebrahimzadeh Parvaneh (dr.parvaneh.ez@gmail.com)
kazemnejad kazem (kazemnejad@goums.ac/ir)

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

E-mail to the introduced people that contains the requested information and an explanation on how to use the desired information.

Comments