Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of intravenous ketamine and intravenous tramadol in the prevalence of shivering after spinal anesthesia in urological surgeries

Protocol summary

Study aim

Comparison of the effect of Intravenous Ketamine and Intravenous Tramadol on the Incidence of Shivering after Spinal Anesthesia in Urological Surgeries

Design

A randomized, triple-blind, controlled clinical trial will be conducted in phase 3 on 90 patients. Excel software will be used for block randomization using the rand function.

Settings and conduct

It is a three-blind clinical trial with a statistical population of 90 patients who are candidates for urology surgery, under spinal anesthesia, in Shahid Hashminejad Medical Training Center. Patients are randomly divided into three groups of 30 people. The anesthesia method will be the same for all patients; With the difference that, at the same time, intravenous ketamine with a dose of 0.5 mg/kg will be administered to the ketamine group, intravenous tramadol with the same dose to the tramadol group, and 0.9% normal saline to the placebo group. The intensity of the patient's shivering, within two hours after the operation, at any moment when the patient has shivering symptoms; will be recorded. Patients, researchers and statistical analysts will be unaware of the patients' groups and treatments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age group: 18 to 70 years old ASA classification: class I, II, and III Exclusion criteria: Patients with contraindications to spinal anesthesia, Personal dissatisfaction

Intervention groups

The intervention groups include patients with tremors who receive intravenous ketamine with a dose of 0.5 mg/kg and intravenous tramadol with the same dose. The comparison or control group includes patients with tremors who receive a placebo (normal saline) intervention.

Main outcome variables

The main outcome of this research: Recording the severity of patient shivering in the questionnaire, within two hours after the surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231021059799N1**
Registration date: **2024-04-15, 1403/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-15, 1403/01/27**
Update count: **0**

Registration date

2024-04-15, 1403/01/27

Registrant information

Name

Siavash Sangi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 5954

Email address

siavashsangi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-09, 1403/01/21

Expected recruitment end date

2024-05-10, 1403/02/21

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of intravenous ketamine and intravenous tramadol in the prevalence of shivering after spinal anesthesia in urological surgeries

Public title
Comparison of the effects of intravenous ketamine and intravenous tramadol in the prevalence of shivering after spinal anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age group: 18 to 70 years old Physical status according to ASA classification classes I, II, and III
Exclusion criteria:
Patients with contraindications to spinal anesthesia and presence of infection at the site of spinal anesthesia injection, Lack of personal consent, Obesity with BMI > 38 kg/m2, Uncontrolled type 1 and 2 diabetes mellitus, Uncontrolled hypertension history, Moderate to severe valvular heart diseases, Neurological and psychiatric disorders such as stroke, history of brain lesions, obsessive-compulsive disorder, and schizophrenia, Fever exceeding 37.5 degrees Celsius at the beginning of the surgery, Patients with sensitivity to ketamine and its derivatives, Patients with sensitivity to tramadol and its derivatives, History of alcohol consumption, drug abuse, or misuse of sedatives-hypnotics and glucocorticosteroids, Presence of fungal and viral infections, Excessive bleeding, Receipt of blood products, Prolonged surgery duration exceeding three hours, History of recurrent nausea and vomiting following previous urological surgeries, Patients whose operating room drapes become wet during surgery.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Allocation: In this study, a randomized block method is utilized using six-member blocks with random order. Then, patients meeting the inclusion criteria will be allocated to groups based on block randomization. (In this method, treatment blocks will be randomly rotated, generating various permutations with blocks of six for three groups, such as ABCABC-BACABC-ABCBAC-ABCCBA... and these permutations will continue until the sample size is reached). Blocks will be randomly selected using Excel software and provided to a researcher who has no involvement in intervention selection. A numerical code will be assigned to each of the created randomization chains. Then, the drug regimen will be packed according to the randomization chains, and after sealing the packets, a unique code will be written on them, and these packets will be randomly placed in a box. The generated code for patients and the type of drug regimen received will also be recorded and maintained by the study epidemiologist who has access to the randomization chain.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This research will be triple blind. Because the patients are unconscious, they are unaware of the type of intervention received. The researcher will be unaware of the type of interventions. an examiner who checks the degree of shivering before and after treatment; will be unaware of the group and treatments of the patients, and there will be a briefing session on how to fill in the questionnaire items (especially the qualitative variables) for the people who are in charge of collecting the samples; will be held Also, the statistical analyst will be unaware of the group and treatments of the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Hemmt Ave, Department of Anesthesia Technology, School of Allied Medical Sciences, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2024-01-01, 1402/10/11
Ethics committee reference number
IR.IUMS.REC.1402.879

Health conditions studied

1

Description of health condition studied
Post Anesthesia Shivering
ICD-10 code
T88.5
ICD-10 code description
Other complications of anesthesia

Primary outcomes

1

Description
shivering after spinal anesthesia in urological surgeries
Timepoint
The severity of patient's shivering will be recorded in the questionnaire every two hours post-operation and at any moment tremor symptoms occur in the patient.
Method of measurement
The valid criterion for the grading of shivering is based on the 5-point scoring system of Crossley Mahajan.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Patients who immediately receive an intravenous dose of ketamine at a dose of 0.5 mg/kg after spinal anesthesia will be referred to as the ketamine group.
Category
Prevention

2

Description
Intervention Group: Patients who immediately receive an intravenous dose of tramadol at a dose of 0.5 mg/kg after spinal anesthesia will be referred to as the tramadol group.
Category
Prevention

3

Description
Control Group: Patients who immediately after spinal anesthesia receive normal saline in the same volume as the drug injected to the intervention groups will be prescribed as the placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hasheminejad Kidney Center
Full name of responsible person
Mehrdad Mesbah Kiaei
Street address
Vali Asr Street, above Vanak Square, Shahid Valinejad Alley, Hashemi Nejad Hospital.
City
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1969714713
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hkc.iran2023@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shahnam Sedigh Maroufi
Street address
Shahid Hemmat Highway, between Sheikh Fazlollah Noori intersection and Shahid Chamran intersection, Iran University of Medical Sciences, School of Para-medicine.
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Email
paramedicine@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences

Full name of responsible person

Siavash Sangi

Position

Msc of Anesthesia Education Student

Latest degree

Master

Other areas of specialty/work

Msc of Anesthesia Education Student

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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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data, such as information related to the main outcome or similar, can be shared.

When the data will become available and for how long

Access period 6 months after publication of results.

To whom data/document is available

It will be available only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

No special conditions are considered.

From where data/document is obtainable

The person responsible for the study of Siavash Sangi. siavash sangi@gmail.com

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

After receiving the applicant's email, the documents will be sent in a short period of time.

Comments