

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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/m<sup>2</sup>, 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-ABCBCA-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

Tehran

##### Province

Tehran

##### Postal code

1969714713

##### Phone

+98 21 81161

##### Email

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 Paramedicine.

##### City

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##### Province

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1449614535

##### Phone

+98 21 8670 4711

##### 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

**Street address**

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**Person responsible for scientific 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**

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**