

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of simultaneous infusion of lidocaine and ketamine compared to single infusion of lidocaine and ketamine on neuromonitoring in spine surgeries

#### Protocol summary

##### Study aim

Investigating the effect of simultaneous infusion of lidocaine and ketamine compared to single infusion of lidocaine and ketamine on neuromonitoring in spine surgeries

##### Design

Clinical trial with 3 groups, with parallel groups, triple blind, randomized, phase 3 on 90 patients. For randomization, a simple randomization method is used using a table of random numbers.

##### Settings and conduct

After the approval of the ethics committee and obtaining the consent of the patients, 90 candidates for spine surgery in Imam Hossein Hospital who meet the entry criteria will be included in the study. Patients are assigned to one of the 3 groups by simple randomization method. Individuals responsible for randomization from the research team will not be responsible for examining the dependent variable. The data analyst will not know about the coding of the groups.

##### Participants/Inclusion and exclusion criteria

Candidate patients for spine surgery under neuromonitoring with the following criteria Age 18 to 65 years Patients with ASA class 1 or 2 Absence of any significant laboratory disturbance in coagulation, kidney, liver function tests, blood cell count No history of drug addiction Insensitivity to ketamine or local anesthetics. Absence of contraindications for performing MEP (epilepsy, cerebral cortex damage, increased intracranial pressure, cardiac pacemaker, intracranial electrodes, or vascular clamps)

##### Intervention groups

After undergoing general anesthesia, patients are assigned to one of three groups: ketamine, lidocaine, or simultaneous infusion, which are administered during the operation. The infusion is halted at the onset of skin closure.

#### Main outcome variables

Latency and amplitude changes in neuromonitoring

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230204057318N2**

Registration date: **2023-07-16, 1402/04/25**

Registration timing: **prospective**

Last update: **2023-07-16, 1402/04/25**

Update count: **0**

##### Registration date

2023-07-16, 1402/04/25

##### Registrant information

##### Name

Alireza Shakeri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7343 0000

##### Email address

dr.alirezashakeri@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of simultaneous infusion of lidocaine and ketamine compared to single infusion of lidocaine and ketamine on neuromonitoring in spine surgeries

**Public title**  
Investigating the effect of simultaneous infusion of lidocaine and ketamine compared to single infusion of lidocaine and ketamine on neuromonitoring in spine surgeries

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Candidate patients for spine surgery under neuromonitoring Age 18 to 65 years Patients with ASA class 1 or 2  
**Exclusion criteria:**  
Absence of any significant laboratory disturbance in coagulation, kidney, liver function tests, blood cell count No history of drug addiction Insensitivity to ketamine or local anesthetics Absence of contraindications for performing MEP (epilepsy, cerebral cortex damage, increased intracranial pressure, cardiac pacemaker, intracranial electrodes, or vascular clamps)

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
For randomization, a simple randomization method was used using a table of random numbers and through the Random generator program of the Android version. In this randomization, patients who meet the criteria for entering the study are assigned a number before anesthesia, which will represent one of the three study groups. Based on this number, special medicine will be started for the patients.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Due to the fact that the patients are unaware of the drug content, they are blinded to their group. Also, the drugs were prepared by a person outside the study group and the treatment group of patients with numbers, so the

treatment group is also unaware of the colorless drug content in the 50 cc syringe. Also, the person who measures pain, nausea, and agitation in recovery is also blinded to the patient group. The data analyst will not know about the coding of the groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

**Street address**

Yaman st., Shahid Chamran Hwy.

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2023-06-27, 1402/04/06

**Ethics committee reference number**

IR.SBMU.MSP.REC.1402.126

## Health conditions studied

### 1

**Description of health condition studied**

Neuromonitoring status in spine surgeries

**ICD-10 code**

M43.2

**ICD-10 code description**

Fusion of spine

## Primary outcomes

### 1

**Description**

Latency and amplitude changes in neuromonitoring

**Timepoint**

During surgery

**Method of measurement**

Analysis of neural wave diagram

## Secondary outcomes

## 1

### **Description**

Intraoperative hemodynamic

### **Timepoint**

During surgery

### **Method of measurement**

Hemodynamic monitoring device

## 2

### **Description**

Intraoperative hemorrhage

### **Timepoint**

During surgery

### **Method of measurement**

Suction bottle and gauzes

## 3

### **Description**

Emergence time from anesthesia

### **Timepoint**

During surgery

### **Method of measurement**

Chronometer

## 4

### **Description**

Pain in the recovery room

### **Timepoint**

Recovery

### **Method of measurement**

Visual Analogue Scale (VAS)

## 5

### **Description**

First time of analgesia request

### **Timepoint**

Post surgery

### **Method of measurement**

Watch

## 6

### **Description**

Postoperative nausea and vomiting

### **Timepoint**

Recovery room

### **Method of measurement**

Questionary

## 7

### **Description**

Sedation - agitation status

### **Timepoint**

Recovery room

### **Method of measurement**

Riker Sedation- Agitation Scale

## **Intervention groups**

### 1

#### **Description**

Intervention group: After general anesthesia in the ketamine group, 0.3 mg/kg/h of ketamine will be administered during the operation and will be stopped at the beginning of skin closure.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: After general anesthesia in the lidocaine group, 1mg/kg/h of lidocaine will be administered during the operation and will be stopped at the beginning of skin closure.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Intervention group: After general anesthesia in the mixed group, 1mg/kg/h of lidocaine and 0.3 mg/kg/h of ketamine will be administered during the operation and will be stopped at the beginning of skin closure.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Hossein Hospital

##### **Full name of responsible person**

Alireza Shakeri

##### **Street address**

Shahid Madani st, Imam ali Hwy.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1617763141

##### **Phone**

+98 21 7343 0000

##### **Email**

dr.alirezashakeri@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Afshin Zarghi

**Street address**

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2243 9331

**Email**

zarghi@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Shakeri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Hossein Hospital, Shahid Madani st, Imam Ali Hwy.

**City**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Shakeri

**Position**

Assistant professor

**Latest degree**

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**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**

There is no more 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**

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