

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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Tehran

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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.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Alireza Shakeri

Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Alireza Shakeri

Position

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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