Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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.
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Tehran
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1617763141
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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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1983963113

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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

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Latest degree
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Person responsible for updating data

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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