Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of magnesium sulfate and bupivacaine on dexmedetomidine and bupivacaine in the epidural block of patients undergoing orthopedic surgery

Protocol summary

Study aim

According to the results of this study, it is possible to choose a drug with appropriate efficiency and minimal harm as an additive to bupivacaine in terms of duration of sensitivity of sensory and motor block, time of block onset and side effects in epidural anesthesia for lower limb surgery.

Design

A double-blind, randomized, phase 3 clinical trial on 50 patients, the random permutation block method is used for randomly assigning patients to study groups, and finally, the data collected for data analysis from + tests (If necessary, Mann-Whitney) and chi-square test will be used, and if necessary, linear regression and logistic regression will be used for multivariate data analysis, and all analyzes will be done using spss version 20 software.

Settings and conduct

Upon entering the operating room, the research is explained to all the participants and they are assured about the confidentiality of the information, then after obtaining permission from the patients, a written consent form is obtained to enter the study using the information in the file. Medicine, medical history of patients is collected.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients aged 18-60 years with anesthesia risk ASA I, II candidates for lower limb orthopedic surgery, exclusion criteria include patients with local infection at the site of epidural block, patients who are allergic to the study drugs, patients who during The operation requires receiving analgesia, patients whose epidural block failed and were subjected to general anesthesia.

Intervention groups

BD group underwent epidural block with bupivacaine and dexmedetomidine and BM group underwent epidural block with bupivacaine and magnesium sulfate.

Main outcome variables

Visual Analogue Scale (VAS) Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231114060049N1**
Registration date: **2023-11-14, 1402/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-14, 1402/08/23**
Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name

nelya reza gholi dehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 613 0524

Email address

nelya.dehkordi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-14, 1401/12/23

Expected recruitment end date

2024-05-12, 1403/02/23

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of magnesium sulfate and bupivacaine on dexmedetomidine and bupivacaine in the epidural block of patients undergoing orthopedic surgery

Public title
Comparing the effect of magnesium sulfate with dexmedetomidine in epidural block with bupivacaine half percent
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18-60 year old patients with anesthesia risk ASA I,II candidates for lower limb orthopedic surgery
Exclusion criteria:
Patients with local infection at the site of epidural block Patients who are allergic to the study drugs Patients who need to receive analgesia during surgery Patients whose epidural block failed and underwent general anesthesia
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the patients are randomized and based on the quadruple permutation block method.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient, the doctor and the person who fills in the questionnaire do not know how people are placed in the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan hospital, Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan hospital,Golestan Ave,Golestan town
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2023-03-14, 1401/12/23
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.204

Health conditions studied

1

Description of health condition studied
orthopedic surgery
ICD-10 code
Y83.1
ICD-10 code description
Surgical operation with implant of artificial internal device as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Pain
Timepoint
After the operation, from the time the level of anesthesia reached T12 to the time of the first application of anesthesia, it was recorded every 30 minutes.
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
blood pressure
Timepoint
It is recorded immediately after the block and every 5 minutes in the first 30 minutes and every 15 minutes until the end of the sensory and motor block.
Method of measurement
Reading from the monitoring device

2

Description

It is recorded immediately after the block and every 5 minutes in the first 30 minutes and every 15 minutes until the end of the sensory and motor block.

Timepoint

It is recorded every 15 minutes until the end of the sensory and motor block.

Method of measurement

Reading from the monitoring device

3

Description

Oxygen Saturation (sat O2)

Timepoint

It is recorded immediately after the block and every 5 minutes in the first 30 minutes and every 15 minutes until the end of the sensory and motor block.

Method of measurement

Reading from the monitoring device

4

Description

Length of effect of sensory block

Timepoint

It is measured every 15 minutes

Method of measurement

Until the sensory level reaches L5.

5

Description

Engine block effect length

Timepoint

The first 30 minutes are recorded every 5 minutes and then every 30 minutes until the Modified Bromage Scale number reaches zero.

Method of measurement

Time

6

Description

The first time the medicine is needed after the operation

Timepoint

The first time when the patient needs pain medication after the operation

Method of measurement

Time

Intervention groups

1

Description

Intervention group: BD group is subjected to epidural block with bupivacaine and dexmedetomidine.

Category

Treatment - Drugs

2

Description

Intervention group: BM group are subjected to epidural block with bupivacaine and magnesium sulfate.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room of Golestan Hospital

Full name of responsible person

Reza Akhondzadeh

Street address

24 metery street, east sahely highway, ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 916 113 5201

Email

akhondzadeh-r@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

Street address

University of medical science, Golestan street, Golestan town، Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 916 613 0524

Email

nelya.dehkordi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Reza Akhondzadeh
Position
Professor of Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
24 metery street, east sahely highway, ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 916 113 5201
Email
akhondzadeh-r@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Reza Akhondzadeh
Position
Professor of Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
24 metery street, east sahely highway, ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 916 113 5201
Email
akhondzadeh-r@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Reza Akhondzadeh
Position
Professor of Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
24 metery street, east sahely highway, ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 916 113 5201
Email
akhondzadeh-r@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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