

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of Bupivacaine plus Magnesium Sulfate with Ropivacaine plus Magnesium Sulfate infiltration on postoperative pain in patients undergoing lumbar laminectomy with general anesthesia

Protocol summary

Study aim

The purpose of this study will be to assess comparison the effect of Bupivacaine plus Magnesium Sulfate with Ropivacaine plus Magnesium Sulfate infiltration on postoperative pain in patients undergoing lumbar laminectomy with general anesthesia

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 3-2.

Settings and conduct

In Urmia Imam Khomeini hospital operating room the patients needing to elective lumbar laminectomy will be divided into two parallel groups (30 patients per group). Before starting anesthesia patients in the first group 70 mg ropivacaine 14 ml plus 1 ml magnesium sulfate 500 mg volume up to 20 ml with normal saline will be injected intravenously. In second intervention group 70 mg of 14 ml bupivacaine plus 1 ml of 500 mg magnesium sulfate up to 20 ml with normal saline will be injected . Each of the medicines will be provided by an anesthetic technician in 20 ml syringes of the same type and neither anesthetist nor orthopedic specialist will be informed of its content.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 18 to 65 years, American Society of Anesthesiologists physical status classification I and II, lumbar laminectomy with general anesthesia Inclusion criteria: Body mass index more than 35 kg/m², Allergy to the drugs studied, Seizure disease, Severe systemic disease, Coagulation Disorders, mental Disorders, A history of drug addiction

Intervention groups

In first intervention group 70 mg ropivacaine 14 ml plus 1 ml magnesium sulfate 500 mg volume up to 20 ml with normal saline will be injected intravenously. In second intervention group 70 mg of 14 ml bupivacaine plus 1 ml

of 500 mg magnesium sulfate up to 20 ml with normal saline will be injected

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N18**

Registration date: **2020-01-07, 1398/10/17**

Registration timing: **retrospective**

Last update: **2020-01-07, 1398/10/17**

Update count: **0**

Registration date

2020-01-07, 1398/10/17

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Bupivacaine plus Magnesium Sulfate with Ropivacaine plus Magnesium Sulfate infiltration on postoperative pain in patients undergoing lumbar laminectomy with general anesthesia

Public title

Evaluation the effects of Bupivacaine plus Magnesium Sulfate with Ropivacaine plus Magnesium Sulfate infiltration on postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

aged 18 to 65 years American Society of Anesthesiologists physical status classification I and II lumbar laminectomy with general anesthesia

Exclusion criteria:

Body mass index more than 35 kg/m² Allergy to the drugs studied Seizure disease Severe systemic disease Coagulation Disorders mental Disorders A history of drug addiction

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be randomly assigned into two groups of Magnesium Sulfate and and Bupivacaine (group BS) and Rupivacaine and Magnesium Sulfate (group RS) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist will be unaware of which patient will be assigned to which group. Syringes will be identical and only the operating room nurse will knew about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-01-16, 1397/10/26

Ethics committee reference number

IR.UMSU.REC.1397.414

Health conditions studied**1****Description of health condition studied**

pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes**1****Description**

pain

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Mean Arterial Blood Pressure

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

None Invasive Blood Pressure

2

Description

Mean pulse Rate

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Electrocardiogram

Intervention groups

1

Description

Intervention group: 70 mg ropivacaine 14 ml plus 1 ml magnesium sulfate 500 mg volume up to 20 ml with normal saline

Category

Treatment - Drugs

2

Description

Intervention group: 70 mg of 14 ml bupivacaine plus 1 ml of 500 mg magnesium sulfate up to 20 ml with normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital, C operating room

Full name of responsible person

Shahryar Sane

Street address

Modarres Boulevard, Ershad Boulevard

City

Uemia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3346 9931

Fax

+98 44 3346 8967

Email

sanesh@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax

+98 44 3223 4897

Email

research@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

sanesh@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Fax**Email**

sanesh@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Emergrnt Street, Resalat Boulevard

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 4897

Email

sanesh@umsu.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

Not applicable

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