# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 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 devided 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)
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+98 44 3223 4897
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**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
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**
Target 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 commitee 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
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Modarres Boulevard, Ershad Boulevard
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## Sponsors / Funding sources

**1**

**Sponsor**
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Oroumia University of Medical Sciences
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Iraj Mohebbi
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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**
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**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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