

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparative study of the effect of adding magnesium, neostigmine and fentanyl to ropevacaine on the properties of motor sensory block in lower extremity surgery under spinal anesthesia

#### Protocol summary

##### Study aim

Comparative study of the effect of adding magnesium, neostigmine and fentanyl to ropevacaine on the properties of motor sensory block in lower extremity surgery under spinal anesthesia

##### Design

Clinical trial without control group with parallel, randomized, phase 3 groups per 100 patients

##### Settings and conduct

This study is performed in Kashani Hospital in Isfahan. Patients are divided into two groups. The first group receives magnesium, neostigmine, and fentanyl, as well as ropevacaine, during anesthesia. The second group receives only rupee and vaccine. Patients' pain will be measured at the desired times.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 65 years, patient agreement with spinal anesthesia, lower limb surgery. Exclusion criteria: presence of infection at the injection site, coagulation disorders, high intracranial pressure, neurological disease.

##### Intervention groups

Intervention group 1: Patients in this group are candidates for elective lower extremity surgery under spinal anesthesia and receive magnesium, neostigmine and fentanyl in addition to ropevacaine during anesthesia. Patients' pain is measured by a visual analog scale questionnaire for 1 hour, 3 hours and 6 hours after surgery and during surgery and will be compared with another group. Intervention group 2: Patients in this group are candidates for elective lower extremity surgery under spinal anesthesia and receive rupee and cocaine during anesthesia. Patients' pain is measured by a visual analog scale questionnaire for 1 hour, 3 hours and 6 hours after surgery and during surgery and will be compared with another group.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200217046523N11**

Registration date: **2021-03-03, 1399/12/13**

Registration timing: **prospective**

Last update: **2021-03-03, 1399/12/13**

Update count: **0**

##### Registration date

2021-03-03, 1399/12/13

##### Registrant information

##### Name

Aryan Rafiee Zadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3837 1582

##### Email address

rafieezadeh.a@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-20, 1400/01/31

##### Expected recruitment end date

2021-06-21, 1400/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparative study of the effect of adding magnesium, neostigmine and fentanyl to ropivacaine on the properties of motor sensory block in lower extremity surgery under spinal anesthesia

## Public title

The effect of magnesium, neostigmine and fentanyl and ropivacaine on the characteristics of motor sensory block

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age between 18 and 65 years Patient agrees to spinal anesthesia Lower limb surgery

### Exclusion criteria:

Infection at the injection site Existence of coagulation disorders High intracranial pressure Having a neurological disease

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Esfahan university of Medical sciences

##### Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

##### City

Isfahan

##### Province

Isfahan

## Postal code

۸۱۳۷۸۶۶۵۱۵

## Approval date

2020-09-04, 1399/06/14

## Ethics committee reference number

IR.MUI.MED.REC.1399.460

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

G89

#### ICD-10 code description

Pain, not elsewhere classified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

1 hour, 3 hours and 6 hours after surgery

#### Method of measurement

Visual Analogue Scale questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Patients in this group are candidates for elective lower extremity surgery under spinal anesthesia and receive magnesium, neostigmine and fentanyl in addition to ropivacaine during anesthesia. Patients' pain is measured by a visual analog scale questionnaire for 1 hour, 3 hours and 6 hours after surgery and during surgery and will be compared with another group.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Patients in this group are candidates for elective lower extremity surgery under spinal anesthesia and receive ropivacaine and fentanyl during anesthesia. Patients' pain is measured by a visual analog scale questionnaire for 1 hour, 3 hours and 6 hours after surgery and during surgery and will be compared with another group.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Kashani hospital

**Full name of responsible person**

Mojtaba Rahimi

**Street address**

آدرس خیابان No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0042

**Email**

parsa.alinezhad85@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjoo

**Street address**

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0042

**Email**

haghjoo.sh@med.mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mojtaba Rahimi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0042

**Email**

parsa.alinezhad85@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mojtaba Rahimi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0042

**Email**

parsa.alinezhad85@gmail.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mojtaba Rahimi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0042

**Email**

parsa.alinezhad85@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can be shared after people have requested.

**When the data will become available and for how long**

Six months after publishing the results.

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Scientific uses

**From where data/document is obtainable**

Isfahan University of Medical Sciences website

**What processes are involved for a request to access data/document**

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

**Comments**