Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ropevacaine on the properties of motor sensory block in lower extremity surgery under spinal anesthesia

Public title
The effect of magnesium, neostigmine and fentanyl and ropevacaine 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
Isfehan
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 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.

Category
Treatment - Drugs

2

Description
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.

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
Isfehan

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
Isfehan

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
Isfehan

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
Isfehan

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
Isfehan
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