

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effects of adding intrathecal neostigmine or magnesium sulphate to bupivacaine in patients under lower extremities surgeries.

Protocol summary

Summary

In this double-blind randomized clinical trial, 90 patients, candidate for lower extremities surgeries in a training hospital, were recruited. The patients with ASA class I and II aging from 20 to 65 years between 2009 and 2010 were evaluated. The selected patients were randomly assigned to receive either bupivacaine alone (Group A, n=30), or bupivacaine plus magnesium sulphate 50% (Group B, n=30), or bupivacaine plus neostigmine (Group C, n=30). The sensory block onset, top level of sensory block, motor block onset, and the completion of motor block and recovery were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071910336N1**

Registration date: **2012-08-15, 1391/05/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-15, 1391/05/25

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Vice- Chancellor for research Poorsina St, Enghelab Ave, Tehran university of medical science

Expected recruitment start date

2010-02-24, 1388/12/05

Expected recruitment end date

2011-11-15, 1390/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of adding intrathecal neostigmine or magnesium sulphate to bupivacaine in patients under lower extremities surgeries.

Public title

Effects of adding intrathecal neostigmine or magnesium sulphate to bupivacaine in patients under lower extremities surgeries.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: The inclusion criteria were patients between 20-65 years who were candidates for lower extremity surgeries and signed informed consent. Exclusion criteria: local infection; hemorrhagic disorders; drug hypersensitivity; muscular disorders; central and peripheral neuropathy; drug abuse history and addiction.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences

Street address

16 Azar St. pardis poor sina

City

Tehran

Postal code

15168

Approval date

2009-08-20, 1388/05/29

Ethics committee reference number

1515

Health conditions studied

1

Description of health condition studied

Contusion of other and unspecified parts of foot

ICD-10 code

S90.3

ICD-10 code description

Contusion of other and unspecified parts of foot

Primary outcomes

1

Description

Sensory block onset

Timepoint

Every 30 second

Method of measurement

Second

Secondary outcomes

1

Description

Recovery of sensory block

Timepoint

Every 5 minute

Method of measurement

Minute

Intervention groups

1

Description

magnesium sulphate 50% Pasteur Institute, Tehran, Iran, singel dose Intrathecal.

Category

Treatment - Drugs

2

Description

neostigmine 0.5 mg/ml (1 ml) Caspian Tamin Co. Rasht, Iran singel dose Intrathecal.

Category

Treatment - Drugs

3

Description

Bupivacaine 0.5% intrathecal injection(Astra-Zeneca)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat rasool hospital

Full name of responsible person

Poopak Rahimzadeh

Street address

niayesh st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor of research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotuhi

Street address

Enghelab St, Poorsina Ave

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Grant name

Grant code / Reference number

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

Title of funding source
Vice-Chancellor of research, Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty