# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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)

**Phone**

+98 21 2226 4036

**Email address**

p_rahimzadeh@tums.ac.ir

**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 scinces
**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.
**City**
Tehran

## 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

**City**
Tehran
**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**
Tehran University Of Medical Sceinces
**Full name of responsible person**
Hamid Reza Feiz
**Position**
Assistant professor
**Other areas of specialty/work**
**Street address**
Hazrat Rasool Hospital Niayesh St.
**City**
Tehran
**Postal code**
15168
**Phone**
+98 21 6435
**Fax**
+98 21 2288 3522
**Email**
hrfeiz@hotmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tehran University Of Medical Sceinces
**Full name of responsible person**
Poupak Rahimzadeh
**Position**
Assistant professor
**Other areas of specialty/work**
**Street address**
Hazrat Rasool Hospital Niayesh St.
**City**
Tehran
**Postal code**
15168
**Phone**
+98 21 2226 4036
**Fax**
+98 21 2226 4036
**Email**
p-rahimzadeh@tums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Birjand University Of Medical Sciences
**Full name of responsible person**
Pooya Derakhshan
**Position**
Assistant professor
**Other areas of specialty/work**
**Street address**
No. 15 Farhang St. Ghafari St.
**City**
Birjand
**Postal code**
15168
**Phone**
+98 56 1442 2409
**Fax**
+98 56 1442 2409
**Email**
pooyaderakh@yahoo.com
**Web page address**

## 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*