

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Low Dose Intrathecal Neostigmine in spinal anesthesia for lower abdominal surgery

Protocol summary

Study aim

Determining the effects of low intraocular neostigmine in spinal anesthesia in lower abdominal surgery

Design

In this research, 90 patients who were Categorized for lower abdominal surgery with spinal anesthesia and referred to Emam Reza Hospital were chosen. Then, patients were randomly divided into three groups of control and intervention .

Settings and conduct

This study was performed in Imam Reza Hospital in Mashhad. The patient and anesthetist nurse were not aware from the type of drug and the groups.

Participants/Inclusion and exclusion criteria

After obtaining the approval of the University Ethics Committee and the satisfaction of patients with ASA I, II, candidates for lower abdominal surgery in the age range of 20-60 years old entered the study.

Intervention groups

Group1: Neostigmine 5 µg (0.1 ml) (chemotherapy drug) with 3 ml of Hyperbaric bupivacaine (15 mg) and 20 µg fentanyl (0.4 ml). Group2: 3 ml of Hyperbaric bupivacaine in interatcal and 0.5 ml of normal saline
Group3: 3 ml bupivacaine Hyperbaric (15 mg) and 25 µg fentanyl (0.5 ml)

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170429033680N6**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **retrospective**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Farideh Golhasani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3802 2631

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golhasanif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-10-30, 1396/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Low Dose Intrathecal Neostigmine in spinal anesthesia for lower abdominal surgery

Public title

Effects of Low Dose Intrathecal Neostigmine in spinal anesthesia for lower abdominal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age between 20-60 years-old Candidate for lower abdominal surgery ASA I,II

Exclusion criteria:
Spinal anesthetic contraindication Pregnant mothers

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
90 patients were randomly assigned to random number generator (Wichmann and Hill, 1982, modified by Mcleod, 1985) from the WWW.randomization.com site and evenly divided into three groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Anesthesiologist nurse and patient are not aware of the groups and type of used drug.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical Sciences; International Offic Administration Center(Qoreishi Building) ; Daneshgah St., Mashhad Mashhad Khorasan Razavi Iran, 13944-91388

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13944-91388

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.MUMS.REC.1394.208

Health conditions studied

1

Description of health condition studied

Abdominal Surgery

ICD-10 code

ICD-10-CM

ICD-10 code description

Lower abdominal pain, unspecified

Primary outcomes

1

Description

PAIN

Timepoint

After operation

Method of measurement

VAS scale

Secondary outcomes

1

Description

heart beat

Timepoint

during operation

Method of measurement

Heart contraction

2

Description

blood pressure

Timepoint

during operation

Method of measurement

device

Intervention groups

1

Description

Intervention group: Neostigmine 5 µg (0.1 ml) (chemotherapy drug) with 3 ml bupivacaine Hyperbaric (15 mg)(Marcaine_, AstraZeneca, Sweden) and 20 µg fentanyl (0.4 ml)) Chemotherapy Company.

Category

Prevention

2

Description

Control group: 3 ml of Hyperbaric bupivacaine in interatcal and 0.5 ml of normal saline

Category

Prevention

3

Description

Control group: 3 ml bupivacaine Hyperbaric (15 mg) and 25 µg fentanyl (0.5 ml)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Seyed Morteza Hoseini

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Department of Anesthesiology, Imam Reza Hospital, Square Taghiabad, Khorasan Razavi, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahryar Mirheidari

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Grant name

Vice chancellor for research, Mashhad University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Akipour

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Department of Anesthesiology, Imam Reza (AS) Hospital, Square Taghi-Abad

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

resulte

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

after publishing

To whom data/document is available

people working in academic institutions or people
working

Under which criteria data/document could be used

citation to results

From where data/document is obtainable

sent email to hoseinimr941@mums.ac.ir

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

sent email to hoseinimr941@mums.ac.ir

Comments