Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 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 Candidated for lower abdominal surgery with spinal anesthesia and refered 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
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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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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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Sponsors / Funding sources

1

Sponsor
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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
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Mohammad Akipour
Position
Associate professor
Latest degree
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Other areas of specialty/work
Anesthesiology
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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