

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative study of the prophylactic effect of neostigmine and atropine combination on the occurrence of post-dural puncture headache in patients undergoing spinal anesthesia with control group

Protocol summary

Study aim

Determining the prophylactic effect of neostigmine and atropine combination on the occurrence of post-dural puncture headache in patients undergoing spinal anesthesia with a control group

Design

A randomized double-blinding clinical trial, with the parallel groups

Settings and conduct

In this study, 100 patients will be included as candidates for lower extremity and lower abdomen surgery and will be randomly divided into two groups. Neostigmine and atropine will be used in one group and normal saline in the other. Then the severity of patients' headaches is evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patient consent to participate in the study, American Society of Anesthesiologists classification of I and II, and surgery duration less than 2 hours. Exclusion criteria include taking anticoagulants, presence of nerve damage in limbs and spine, coagulation diseases, history of spinal surgery, spinal canal stenosis and MS, conduction disorders of the heart, history of migraine headaches, addiction to drugs, and a history of malignancy.

Intervention groups

In this study, all patients will undergo spinal block. After performing spinal block and confirming its accuracy, patients in the intervention group will be prescribed a combination of 400 g of neostigmine and 200 g of atropine and in the control group normal saline. Thus, for every 10 kg of patient weight, 1 cc is administered intravenously.

Main outcome variables

Severity of headache, duration of headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N11**

Registration date: **2020-11-09, 1399/08/19**

Registration timing: **prospective**

Last update: **2020-11-09, 1399/08/19**

Update count: **0**

Registration date

2020-11-09, 1399/08/19

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the prophylactic effect of neostigmine and atropin combination on the occurrence of post-dural puncture headache in patients undergoing spinal anesthesia with control group

Public title

The prophylactic effect of neostigmine and atropin combination on the occurrence of post-dural puncture headache in patients undergoing spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent to participate in the study
American Anesthesiologists Association Classification I and II
Duration of surgery less than 2 hours

Exclusion criteria:

Taking anticoagulants
Existence of a nerve lesion in the limb/spine
Coagulation diseases
History of spinal surgery, spinal canal stenosis
Conductive disorders of the heart
History of migraine headaches
Opioid addiction
History of malignancy

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the drug combination of "neostigmine and atropine" and normal saline were prepared by the operating room nurse in the same volume and marked with labels A and B. It is then given daily to the researcher and will be administered accidentally for patients. Therefore, the patient and the researcher will not have any information about the two prescribed drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Azadi Square.

City

Isfaha

Province

Isfahan

Postal code

8174673461

Approval date

2020-06-28, 1399/04/08

Ethics committee reference number

IR.MUI.MED.REC.1399.258

Health conditions studied

1

Description of health condition studied

Lower limb surgery

ICD-10 code

S89.92XA

ICD-10 code description

Unspecified injury of left lower leg, initial encounter

Primary outcomes

1

Description

Pain severity

Timepoint

From first day to seven days after surgery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Duration of headache

Timepoint

From first day to seven days after surgery

Method of measurement

Counting the number of days suffering from headache

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in this group will be subjected to the spinal block as usual. After confirmation of anesthesia, normal saline is administered intravenously

per 10 kg of patient weight.

Category

Placebo

2

Description

Intervention group: Patients in this group will be subjected to the spinal block as usual. After confirmation of the anesthesia, a combination of 400 g of neostigmine and 200 g of pre-prepared atropine is administered intravenously for every 10 kg of patient weight.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Mohammad Golparvar

Street address

Anesthesiology Department, Kashani Hospital,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Mohammad Golparvar

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Golparvar

Position

Professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Ahmadzadeh
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Non-faculty specialist physician
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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