Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

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
Isfehan

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, Kashani Street.

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Isfahan

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8183983434

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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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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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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

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

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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

Position

Non-faculty specialist physician

Latest degree

Medical doctor

Other areas of specialty/work

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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