Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effect of pre-administration with Neostigmine and Atropine on the occurrence of post dural puncture headache in patients undergoing spinal anesthesia in cesarean

Protocol summary

Study aim
Determining the effect of Neostigmine and Atropine on post-dural puncture headache in spinal anesthesia in cesarean

Design
The randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 62 patients

Settings and conduct
In this randomized double-blind clinical trial study, 62 pregnant women candidate for cesarean section with spinal anesthesia referred to Beheshti Hospital in Isfahan will be included in the study and randomly divided into 2 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 include pregnant women candidate for cesarean section with spinal anesthesia, American society of anesthesiologists classification 1 and 2, in the age group of 18 to 45 years, no neurological deficit in limb, spinal cord, no coagulation diseases, no history of spinal cord surgery, spinal canal stenosis and MS, duration of surgery less than 2 hours, no heart conductive disorder, no history of migraine headaches, and patient consent to participate in the study. Exclusion criteria include spinal block failure, change in anesthesia method to general anesthesia bleeding more than 20 cc/kg, and more than 3 punctures.

Intervention groups
Intervention group: All patients will undergo spinal block. After performing the spinal block and confirming its accuracy, patients will be prescribed a combination of 0.5 mg of neostigmine and 0.5 mg of atropine. Thus, for every 10 kg of patient weight, 1 cc is administered intravenously. Control group: All patients will undergo spinal block. After performing the spinal block and confirming its accuracy, normal saline will be prescribed to patients. 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: **IRCT20210324050762N1**
Registration date: **2021-09-24, 1400/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-24, 1400/07/02**
Update count: **0**

Registration date
2021-09-24, 1400/07/02

Registrant information

Name
amir mansoury

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3320 0076

Email address
amir.mansoury75@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-22, 1400/05/31

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pre-administration with Neostigmine and Atropine on the occurrence of post dural puncture headache in patients undergoing spinal anesthesia in cesarean

Public title

Effect of Neostigmine and Atropine on post dural puncture headache in spinal anesthesia in cesarean

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant woman candidate for cesarean section with spinal anesthesia American anesthesiologists association classification I and II Age 18-45 years No neurological deficit in limb, spinal cord and CNS No coagulation diseases No history of spinal cord surgery, spinal canal stenosis and MS Duration of surgery less than 2 hours No heart conductive disorder No history of migraine headaches No anticoagulant drug consumption Consent for spinal block Patient consent to participate in the study

Exclusion criteria:

Spinal block failure Change in anesthesia method to general anesthesia Bleeding more than 20 cc/kg More than 3 punctures

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 62 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

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

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2020-11-24, 1399/09/04

Ethics committee reference number

IR.MUI.MED.REC.1399.749

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Headache severity

Timepoint

From first day to five days after surgery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Duration of headache

Timepoint

From first day to five days after surgery

Method of measurement

Counting the number of days suffering from headache

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients will undergo spinal block. After performing the spinal block and confirming its accuracy, patients will be prescribed a combination of 0.5 mg of neostigmine and 0.5 mg of atropine. Thus, for every 10 kg of patient weight, 1 cc is administered intravenously.

Category

Treatment - Drugs

2

Description

Control group: All patients will undergo spinal block. After performing the spinal block and confirming its accuracy, normal saline will be prescribed to patients. Thus, for every 10 kg of patient weight, 1 cc is administered intravenously.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Lili Adineh Mehr

Street address

Anesthesiology Department, Shahid Beheshti Hospital

City

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8184853541

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy 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

sfahan 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

Lili Adineh Mehr

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Latest degree
Specialist

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Position
Non-faculty general 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