

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of the effectiveness of Atropine-Neostigmine mixture and Ondansetron injection in preventing headache after Cesarean section under spinal anesthesia

Protocol summary

Study aim

Comparison of the effectiveness of atropine-neostigmine mixture injection and ondansetron injection in preventing headache after cesarean section under spinal anesthesia

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. Lottery and sealed envelopes are used for randomization.

Settings and conduct

This is a randomized double-blind clinical trial that will be performed on 60 patients undergoing cesarean section under spinal anesthesia at Beheshti Hospital in Isfahan; After the approval of the university ethics committee and obtaining the patients' consent, the patients entered the groups by random allocation. In each group, the desired intervention is applied and the patient's clinical signs and existing complications are reviewed and recorded. The person who is performing the intervention would be different from the evaluator and they do not know the type of intervention. In spite of the fact that Patients are aware of the study, they are not aware of the type of intervention so they are all blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 45 years old pregnant woman undergoing cesarean section under spinal anesthesia, anesthesia ASA class I and II, and patient informed consent. Exclusion criteria: history of coagulation diseases, presence of nerve damage in limbs, spine, and CNS, history of spinal surgery, MS, and Migraine history.

Intervention groups

Intervention group A: They receive a mixture containing 20 µg/kg Neostigmine and 10µg/kg Atropine 15 minutes before the spinal anesthesia. Intervention group B: They Receive 4 mg of ondansetron 15 minutes before spinal anesthesia. Control group C: They receive 5 ml of distilled water 15 minutes before the spinal.

Main outcome variables

The headache after spinal anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N39**

Registration date: **2022-01-13, 1400/10/23**

Registration timing: **prospective**

Last update: **2022-01-13, 1400/10/23**

Update count: **0**

Registration date

2022-01-13, 1400/10/23

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Atropine-Neostigmine mixture and Ondansetron injection in preventing headache after Cesarean section under spinal anesthesia

Public title

The effect of Atropine-Neostigmine mixture and Ondansetron on headache after Cesarean section under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant woman candidate for cesarean section under spinal anesthesia Age 18 to 45 years ASA class I and II Patient consent to study

Exclusion criteria:

Consumption of anticoagulants Existence of nerve damage in limbs, spine and CNS Having coagulation diseases History of spinal surgery, spinal stenosis and MS Having heart conduction disorders Have a history of migraine headaches

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This is a simple randomized clinical trial in which individuals enter study groups by lottery; The drugs are placed in the desired number in sealed opaque and uniformly sealed bags. Each of the codes is also written on a piece of paper, folded, and placed inside a box. After entering the operating room, each patient takes one of the papers out of the box. Which is applied to the patient. This continues until the end of the paperwork so that the number of patients in the desired volume in the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind clinical trial; In this way, before obtaining consent, patients are studied but do not know which group they will be in and therefore are blind. Also, the nurse who injects the drug and the researcher who

records the patient's symptoms do not know the type of drug and are blind.

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

Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square, Isfahan

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Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-04-07, 1400/01/18

Ethics committee reference number

IR.MUI.MED.REC.1400.009

Health conditions studied**1****Description of health condition studied**

Headache after spinal anesthesia in cesarean

ICD-10 code

O29

ICD-10 code description

Complications of anesthesia during pregnancy

Primary outcomes**1****Description**

The headache after spinal anesthesia in Cesarean

Timepoint

Patients are followed up for headaches for up to seven days after the spinal block. In case of headache in the first 24 hours every 6 hours and then daily, its amount is measured by VAS scale.

Method of measurement

VAS Pain Intensity Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, receive about 2cc/kg/hr serum 1/3-2/3 then 10µg/kg Atropine and 20µg/kg Neostigminr will be injected 15 minutes before the spinal. Then the patient will be positioned in a seating or lateral and spinal anesthesia will be performed. Then patients receive 4-6 liters of oxygen per minute through a face mask and after sensory and motor block surgery will perform. During the operation and in recovery, the patient is monitored for vital signs and related complications.

Category

Prevention

2

Description

Intervention group B: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, receive 2cc/kg/hr of 1/3-2/3 serum, then they are given 4 mg of Ondansetron 15 minutes before the spinal Is injected. Then the patient will be positioned in a seating or lateral and spinal anesthesia will be performed. Then patients receive 4-6 liters of oxygen per minute through a face mask and after sensory and motor block surgery will perform. During the operation and in recovery, the patient is monitored for vital signs and related complications.

Category

Prevention

3

Description

Control group C: In this group, eligible patients, after being placed on a surgical bed and monitoring connection, receive 2cc/kg/hr of serum 1/3-2/3, then they are given 5 ml of distilled water as a placebo 15 minutes before Spinal injection is performed. Then patients receive 4-6 liters of oxygen per minute through a face mask and after sensory and motor block surgery will perform. During the operation and in recovery, the patient is monitored for vital signs and related complications.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Beheshti Hospital

Full name of responsible person

Behzad Nazemroaya

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Shahid Beheshti Hospital , Ostad Motahhari St. , felezi Bridge , Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Behzad Nazemroaya

Position

Assistant Professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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