

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of preoperative intravenous Ondansetron on level and time to regression of sensory and motor block in patients undergoing cesarean section during spinal anesthesia

Protocol summary

Study aim

Effect of preoperative intravenous Ondansetron on level and time to regression of sensory and motor block in patients undergoing cesarean section during spinal anesthesia

Design

The intervention (ondansetron) and the control group (normal saline) Randomization: Simple Sample size: 160 people Clinical trial with control group, with parallel groups, double blind

Settings and conduct

In Qaem Hospital after rule out the long QT syndrome, patients are randomly divided into two groups. Group O received 4 mg (2 cc) of ondansetron(IV) and group S 2 cc normal saline within 1 minute, 15 minutes before the spinal anesthesia(triple blind study). After 15 minutes the patient is in a sitting position and under sterile conditions will be anesthetised at level L3-4 or L4-5 with 2.5 cc bupivacaine . In case of hypotension and decrease of HR more than 20% baseline, ephedrine 5-10 mg bolus and atropine 0.5-1 mg are prescribed. Systolic blood pressure(SBP),diastolic blood pressure(DBP),mean arteial pressure(MAP),heart rate(HR) and pulse oximetry(SpO2) , maximum level of sensory block with blunt needle ,time of reversal of sensory block to S1 and the level of the motor block is also assessed by the Modified Bromage scale are recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria:pregnant womenwho candidate for cesarean section with ASA class 1 who has no history of hearing impairment, neurologic disease, use of alpha-2 agonist or calcium channel blocker analgesia in recent months and no contraindication for spinal and no history of long QT in the individual or family.

Intervention groups

Control group received 2 cc normal saline and

intervention group received 4 mg of ondansetron (2 cc) before spinal anesthesia with bupivacaine.

Main outcome variables

Primary outcomes: sensory and motor block levels,
Secondary outcomes:SBP,DBP,MAP,SpO2 and HR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190327043122N1**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

SALEHEH ASGHARI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3866 2039

Email address

asgharisa@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative intravenous Ondansetron on level and time to regression of sensory and motor block in patients undergoing cesarean section during spinal anesthesia

Public title

Effect of Ondansetron on block of spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

women who candidate for cesarean section without any hearing problems , without neurologic disorders or use of alfa 2 agonists or calcium channel blockers in the last month Have not contraindication criteria for spinal anesthesia Have not history of long QT in the patient and family.

Exclusion criteria:

need to general anesthesia

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients is divided into two equal groups according to the table of random numbers (simple randomization) . In closed envelopes, syringes containing 2 cc of solution are provided by the anesthesiologist. Group A received ondansetron and group B received normal saline .

Blinding (investigator's opinion)

Double blinded

Blinding description

Since the drug form is the same in both groups and the injection method is the same, it is not possible for patients to identify the drug group in the operating room during surgery. The assessor and analyst will also be blinded of the groups. But the researcher that present during surgery will not be blind to the groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Mashhad University of Medical Sciences

Street address

Shareeati Square , Qaem Hospital

City

mashhad

Province

Razavi Khorasan

Postal code

9176699199

Approval date

2019-10-12, 1398/07/20

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.524

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

Effect of ondansetron on level and time to regression of sensory and motor block in spinal anesthesia

ICD-10 code

O74

ICD-10 code description

Complications of anesthesia during labor and delivery

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

level and time to regression of sensory block in spinal anesthesia

Timepoint

Every 2 minutes after spinal anesthesia until fixation of sensory level then every 30 minutes till regression of block to the level of S1.

Method of measurement

blunt niddle

2**Description**

Time to reverse of motor block in spinal anesthesia

Timepoint

Every 30 minutes till regression of motor block

Method of measurement

Table of Modified Bromage scale

Secondary outcomes

1

Description

Systolic blood pressure(SBP)

Timepoint

Before and immediately after spinal anesthesia and every 3 minutes until 30 minutes then every 5 minutes until the end of surgery

Method of measurement

Sphygmomanometer

2

Description

Diastolic blood pressure(DBP)

Timepoint

Before and immediately after spinal anesthesia and every 3 minutes until 30 minutes then every 5 minutes until the end of surgery.

Method of measurement

Sphygmomanometer

3

Description

Mean arterial pressure(MAP)

Timepoint

Before and immediately after spinal anesthesia and every 3 minutes until 30 minutes then every 5 minutes until the end of surgery.

Method of measurement

Sphygmomanometer

4

Description

Heart rate(HR)

Timepoint

Before and immediately after spinal anesthesia and every 3 minutes until 30 minutes then every 5 minutes until the end of surgery.

Method of measurement

Cardiac monitoring(5 leads)

5

Description

pulse oximetry (SpO₂)

Timepoint

Before and immediately after spinal anesthesia and every 3 minutes until 30 minutes then every 5 minutes until the end of surgery.

Method of measurement

pulse oximetry

Intervention groups

1

Description

Intervention group: 4 milligrams(2cc) ondansetron

(IV),15 minutes before spinal anesthesia with 2.5 cc hyperbaric bupivacaine is administered. In the event of a hypotension and bradycardia, more than 20% of the basal, 5-10 milligrams ephedrine and 0.5 to 1 mg atropine is injected , respectively.

Category

Treatment - Drugs

2

Description

Control group: 2cc normal saline (IV),15 minutes before spinal anesthesia with 2.5 cc hyperbaric bupivacaine is administered. In the event of a hypotension and bradycardia, more than 20% of the basal, 5-10 milligrams ephedrine and 0.5 to 1 mg atropine is injected , respectively.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem hospital

Full name of responsible person

Saleheh Asghari

Street address

Shareeati Square,Qaem Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saleheh Asghari

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Grant name

Mashhad University of medical science

Grant code / Reference number

980356

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

Full name of responsible person

Saleheh Asghari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

associated professor

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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

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Informations related to the primary outcomes

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

For people working in academic institutions and businesses

Under which criteria data/document could be used

people working in academic institutions

From where data/document is obtainable

Asgharisa@mums.ac.ir

What processes are involved for a request to access data/document

During 3-5 days

Comments