Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 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
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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 untill 30 minutes then every 5 minutes untill 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 untill 30 minutes then every 5 minutes untill 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 untill 30 minutes then every 5 minutes untill the end of surgery.
Method of measurement
Sphygmomanometer

4

Description
Heart rate(HR)
Timepoint
Before and immediately after spinal anesthesia and every 3 minutes untill 30 minutes then every 5 minutes untill 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 untill 30 minutes then every 5 minutes untill the end of surgery.
Method of measurement
pulse oximetry

Intervention groups

1

Description
Intervention group: 4 miligrames(2cc) ondansetron (IV),15 minutes before spinal anesthesia with 2.5 cc hyperbaric bupivacaine is administered. In the event of a hypotension and bradicardia, more than 20% of the basal, 5-10 milligrames 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 bradicardia, more than 20% of the basal, 5-10 milligrames 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
Street address
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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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Shareeati Square, Qaem hospital

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Person responsible for scientific inquiries

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Position
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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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Latest degree
Specialist

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Anesthesiology

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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
Inforamations 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