Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables and the need for ephedrine in women candidates for cesarean section under spinal anesthesia

Protocol summary

Study aim
Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables in women candidates for cesarean section under spinal anesthesia

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 is performed on 60 patients. Random allocation software version 1.0 is used for randomization under Windows.

Settings and conduct
This study is performed on women candidates for cesarean section under spinal anesthesia in Kosar operating room of Shahid Sadoughi Hospital in Yazd. Prior to spinal anesthesia, the study drug or placebo is injected intravenously and then hemodynamic variables are measured and recorded during surgery and during recovery. This study is double-blind and neither the researcher nor the patient knows the type of drug prescribed, so that the drugs are prepared and coded in three identical syringes and the third person injects the drug for the patient based on the specified code.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women aged 20-35 years, Class I ASA, non-emergency cesarean section, spinal anesthesia Non-inclusion criteria: dissatisfaction with the study, diabetes, preeclampsia and eclampsia, severe heart, lung, kidney and liver disease, drug addiction

Intervention groups
Intervention group1: In this group, granisetron at a dose of 3 mg equivalent to 3 ml is injected slow intravenously immediately before spinal anesthesia. Intervention group 2 : In this group, ondansetron in a dose of 4 mg in a volume of 3 ml is injected slowly into intravenous patients immediately before spinal anesthesia. Control group: In this group, 3 ml normal saline is injected slow intravenously immediately before spinal anesthesia.

Main outcome variables
Systolic blood pressure; diastolic blood pressure; mean arterial blood pressure; heart rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100102002963N35**
Registration date: **2022-03-19, 1400/12/28**
Registration timing: **prospective**

Last update: **2022-03-19, 1400/12/28**
Update count: **0**

Registration date
2022-03-19, 1400/12/28

Registrant information
Name
Shekoufeh Behdad
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 35 1822 1386
Email address
drbehdad@ssu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-05, 1401/02/15
Expected recruitment end date
2022-08-06, 1401/05/15
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables and the need for ephedrine in women candidates for cesarean section under spinal anesthesia

Public title

Comparison of the effect of intravenous ondansetron and granistron with placebo on hemodynamic variables and the need for ephedrine in women candidates for cesarean section under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20-35 years old women with term pregnancy American Society of Anesthesia (ASA) physical status I Non-emergency cesarean delivery Spinal anesthesia

Exclusion criteria:

dissatisfaction with the study diabetes preeclampsia and eclampsia severe heart, lung, kidney and liver disease drug addiction

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly allocate 60 eligible applicants, we randomly divide them into three groups of 20 people. For this purpose, we use Random allocation software version 1.0 under Windows to create a sequence, and by using this software we make A list which is specified from 1 to 60 with group A or B or C treatment By Using this list, we give the first person who is eligible to enter the study, number one and the last person the number 60, then based on the random allocation list and by the software, it is determined which group A or B or C each person is in. Each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug is given to patients by a third person who is not involved in evaluating patients and recording results.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and researchers themselves are unaware of which medication the patient has received, in this way, each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug is given to patients by a third person who is not involved in evaluating patients and recording results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Medical School - Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Faculty of Medicine. Shohadayegomnam Blv.Yazd

City

Yazd

Province

Yazd

Postal code

8915887857

Approval date

2021-11-18, 1400/08/27

Ethics committee reference number

IR.SSU.MEDICINE.REC.1400.474

Health conditions studied

1

Description of health condition studied

Hemodynamic variables and hypotension after spinal anesthesia in the women undergoing cesarean section

ICD-10 code

I95.81

ICD-10 code description

Postprocedural hypotension

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes

Method of measurement

Using monitoring device

2

Description
Diastolic Blood Pressure
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
Method of measurement
Using monitoring device

3

Description
Mean Arterial Pressure
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
Method of measurement
Using monitoring device

4

Description
Heart Rate
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
Method of measurement
Using monitoring device

5

Description
Drop in systolic blood pressure below 90 mm Hg
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes
Method of measurement
Using monitoring device

Secondary outcomes

1

Description
Bradycardia(drop in heart rate below 50/ min)
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
Method of measurement
Using monitoring device

Intervention groups

1

Description
Intervention group 1: In this group, granisetron at a dose of 3 mg equivalent to 3 ml is injected slow intravenously and once immediately before spinal anesthesia to eligible patients.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, ondansetron in a dose of 4 mg in a volume of 3 ml is injected slowly into intravenous patients immediately before spinal anesthesia.
Category
Treatment - Drugs

3

Description
Control group: In this group, 3 ml normal saline is injected slow intravenously and once immediately before spinal anesthesia to eligible patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Dr. Shekoufeh Behdad
Street address
Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd
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behdad90@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person

Dr. Amirhooshang Mehrparvar

Street address
Central building of Yazd University of Medical Sciences, Bahonar Square.

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ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Dr Shekoufeh Behdad

Position
Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Dr Shekoufeh Behdad

Position
Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr. Shekoufeh Behdad

Position
Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd

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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