

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

City

Yazd

Province

Yazd

Postal code

8916886938

Phone

+98 35 3822 4101

Email

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.

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3724 0171

Email

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

Street address

Central building of Yazd University of Medical Sciences, Bahonar Square

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

0098 35 8231932

Email

drbehdad@ssu.ac.ir

Person responsible for scientific 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

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Province

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8915887857

Phone

+98 35 3823 1932

Email

drbehdad@ssu.ac.ir

Person responsible for updating data

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

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Other areas of specialty/work

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City

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Province

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Postal code

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Phone

+98 35 3823 1932

Email

drbehdad@ssu.ac.ir

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