

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the Prophylactic Effect Of Intravenous Ondansetron And Granisetron on Hypotension Induced Through Spinal Anesthesia in Cesarean Delivery

Protocol summary

Summary

The purpose of the study is Comparison of the prophylactic effect of intravenous Ondansetron and Granisetron on hypotension induced through spinal anesthesia in cesarean delivery. Population studied are pregnant women 18 to 45 years that candidate for elective cesarean delivery and have no contraindication for spinal anesthesia. The subjects were divided into 3 groups. O group 5 minutes before spinal anesthesia received 4 mg Ondansetron, G group received 1mg Granisetron and S group received normal saline. The sample size will be 70 in each group and 210 in total. Study is double-blind. Systolic and diastolic blood pressure and mean arterial pressure and heart rate will be record before spinal anesthesia and every 3 minutes to 20 minutes after its. In the event hypotension (systolic blood pressure less than 90mmHg) or bradycardia (heart rate less than 50) will be treated with Ephedrine and Atropine respectively. Nausea, vomiting and chill complaint will be recorded and treated with Metoclopramide and Petedin

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061334519N1**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name

Marzieh Fadaei

Name of organization / entity

Zahedan medical science university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Zahedan university of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Prophylactic Effect Of Intravenous Ondansetron And Granisetron on Hypotension Induced Through Spinal Anesthesia in Cesarean Delivery

Public title

Effect of Granisetron & Ondansetron on induced hypotension of spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women aged 18 to 45 with ASA class1,2 for elective cesarean section under spinal

anesthetical. Exclusion criteria: coagulopathy; hemodynamic impaired; history of allergy to anesthesia or medication drugs are studied; taking SSRI anti-seizure & anti migraine; patients suffering from hypertensive disorder; any contraindication to spinal anesthesia; spinal anesthesia failure Open in Google Translate

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Sampling will be random selection based on the gradual reference of eligible samples. The assignment method will be based on permuted block randomization. Study is double-blind, patients and those who measure the study variables are not aware of the distribution of the groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Zahedan University Of Medical Sciences

Street address

Office complex pardis of Zahedan University Of Medical Sciences university, Square of Dr Hesabi

City

Zahedan

Postal code

9816743463

Approval date

2017-05-28, 1396/03/07

Ethics committee reference number

IR.ZAUMS.REC.1396.36

Health conditions studied

1

Description of health condition studied

cesarian

ICD-10 code

080-082

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Hemodynamic condition

Timepoint

befor of intervension then every 3minutes to 20 minutes

Method of measurement

by monitor device

Secondary outcomes

1

Description

hypotension

Timepoint

befor intervention then every 3minute until 20 minutes

Method of measurement

by the monitor

2

Description

bradycardia

Timepoint

befor intervention then every 3minute until 20 minutes

Method of measurement

by the monitor

3

Description

nausea

Timepoint

when event

Method of measurement

patient complain

4

Description

vomiting

Timepoint

when event

Method of measurement

patient complain

5

Description

chill

Timepoint

when event
Method of measurement
patient complain

Intervention groups

1

Description

O intervention group: 4mg Ondansetron that diluted with 10cc saline normal is injecting intravenously 5 minutes before spinal anesthesia

Category

Treatment - Drugs

2

Description

G group intervention: 1mg Granisetron that diluted with 10cc saline normal is injecting intravenously 5 minutes before spinal anesthesia

Category

Treatment - Drugs

3

Description

control group: 10cc saline normal is injecting 5 minutes before spinal anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebne Abitaleb Hospital

Full name of responsible person

Dr Asadollah Shakeri

Street address

Ali ebne abitaleb hospitsl.Khalije Fars Blvd

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan Medical Science University

Full name of responsible person

Dr Nurmohammad Bakhshani

Street address

. research deputy of Zahedan medical science university, Dr Hesabi squar

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Grant name

-0

Grant code / Reference number

-0

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

Yes

Title of funding source

Vice chancellor for research, Zahedan Medical Science University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan Medical Science University

Full name of responsible person

Dr Marzieh Fadaei

Position

Anesthesia assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty