

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of prophylactic effect of ondansetron and ketamine on spinal anesthesia-induced hypotension in cesarean section

Protocol summary

Summary

Objectives: Among regional anesthesia techniques, spinal anesthesia is more practical due to ease of technique, more speed, reliable nerve block, using minimum dose of local anesthetics, and the cost-effectiveness. However, this method is also associated with complications, and hypotension induced by sympathetic block is the most common of them. Ondansetron, as a serotonin receptor antagonist can reduce hypotension-induced by spinal anesthesia. Next drug is ketamine which is used for analgesia during labor. Ketamine is a N-methyl-D-aspartate (NMDA) receptor antagonist and a common drug used to induce anesthesia in pregnant women. The aim of this study is to compare prophylactic effect of ondansetron and ketamine on spinal anesthesia induced hypotension in cesarean section. Design: Block randomization, triple blind, with placebo, trial phase 2, including 93 patients under elective cesarean section. Setting and conduct: Lidocaine 5%, 75 milligrams, injection into the subdural space to induce spinal anesthesia. Participants including major eligibility criteria: All women who are supposed to undergo elective cesarean section. Intervention: Ondansetron, 4 milligrams (2 ml), slow IV injection in 30 seconds. Ketamine, 25 milligrams (volume 2 ml with distilled water), IV injection. Normal saline, 2 ml, IV injection in control group. Main outcome measures: Systolic blood pressure, diastolic blood pressure, arterial O2 saturation, heart rate, Level of consciousness.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102315137N1**

Registration date: **2014-01-28, 1392/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-28, 1392/11/08

Registrant information

Name

Saeid Bagherbandi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

dr.bagherbandi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic effect of ondansetron and ketamine on spinal anesthesia-induced hypotension in cesarean section

Public title

Comparison of the effects of ondansetron and ketamine on spinal anesthesia-induced hypotension in women

undergoing cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women candidate for elective cesarean with spinal anesthesia who referred to Taleghani hospital, Arak. Exclusion criteria: Dissatisfaction of patient; Hypertension; Cardiovascular diseases; Body mass index upper 35; History of liver disease; History of migraine and seizure; Allergy to ondansetron; History of taking any medications that affect blood pressure or heart rate; Failure of spinal anesthesia; In top spinal cord Injuries; Need to additional drugs

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Injecting person, and the person responsible for collecting data are not aware of injecting drug. Syringes containing drug are prepared by someone else and are only labeled by the letters A, B, and C.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Postal code

Approval date

2013-07-15, 1392/04/24

Ethics committee reference number

14-149-92

Health conditions studied

1

Description of health condition studied

Hypotension

ICD-10 code

I95, I95.0

ICD-10 code description

Hypotension due to drugs

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

Method of measurement

Sphygmomanometer

2

Description

Diastolic blood pressure

Timepoint

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

Method of measurement

Sphygmomanometer

3

Description

Arterial O2 saturation

Timepoint

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

Method of measurement

Pulse oximeter

4

Description

Heart rate

Timepoint

Before spinal anesthesia and every five minutes to thirty minutes after taking drug

Method of measurement

Cardiac monitor

5

Description

Level of consciousness

Timepoint

Before spinal anesthesia and thirty minutes after taking drug

Method of measurement

Ramsay score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1. Ondansetron, 4 milligrams (2 ml), slow IV injection in 30 seconds; made in Tehran Chemistry Pharma Co. with chemical composition (RS)-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-2,3-dihydro-1H-carbazol-4(9H)-one

Category

Prevention

2

Description

Intervention 2. Ketamine, 25 milligrams (volume 2 ml with distilled water), IV injection; made in TRITTAU company, GERMANY, with chemical composition (RS)-2-(2-Chlorophenyl)-2-(methylamino)cyclohexanone

Category

Prevention

3

Description

Intervention 3. Normal saline, 2 ml, IV injection in control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Saeid Bagherbandi

Street address

Taleghani hospital. Imam Khomeini street. Arak. Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Saeed Changizi Ashtiani

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences, Vice Chancellor for Research

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

Arak University of Medical Sciences

Full name of responsible person

Dr Saeid Bagherbandi

Position

Anesthesiology Assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Saeid Bagherbandi

Position

General practitioner

Other areas of specialty/work

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Arak University of Medical Sciences

Full name of responsible person

Dr Saeid Bagherbandi

Position

Anesthesiology resident

Other areas of specialty/work**Street address**

Arak University of Medical Sciences. Basij Square.

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Postal code**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