

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Compare the effect of two different doses of ondansetron in the prevention of headache after spinal anesthesia in pregnant women referred to Taleghani Hospital in Arak

Protocol summary

Summary

This study compared the effect of two doses of ondansetron in the prevention of headache after spinal anesthesia. In this study, 180 pregnant women were randomly divided into 3 groups. Patients in the first group of 8 mg ondansetron, 4 mg ondansetron in the second group and the third group received normal saline will be. The volume of material injected in each group will be equal by using of 5 ml normal saline and there is no apparent difference between them. Medications encoded by a person who is not involved in the study will be ready and patients and residents will be responsible for them and aware of the layout. Category Inclusion criteria were pregnant women 20 to 35 years old, ASA 1-2, body mass index less than 30, and patient exclusion criteria from study will be, cardiovascular disease, contraindications of spinal anesthesia. Oral and written consent will be obtained from all patients. The patient will be under spinal anesthesia with twelve milligrams of Marcaine. The patient will be suitable Positioning, nausea and vomiting, and hypotension in patients treated with atropine and ephedrine. The main variable in this study is a headache after spinal anesthesia which is usually 24 to 48 hours after the puncture of dura starts with the beat in the area of the frontal or occipital sense and often with photophobia, double vision, blurred vision, hearing loss and nausea and vomiting, then all necessary information will be gathered in the certain days of the patient. And the study will be randomized and double-blind at the end of the study ondansetron may be used to control of headache after spinal anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090629732N1**

Registration date: **2017-07-12, 1396/04/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-12, 1396/04/21

Registrant information

Name

Marzieh Shahidani

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor and Research, Arak University of Medical Sciences

Expected recruitment start date

2016-02-05, 1394/11/16

Expected recruitment end date

2016-06-17, 1395/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of two different doses of ondansetron

in the prevention of headache after spinal anesthesia in pregnant women referred to Taleghani Hospital in Arak

Public title

Ondansetron effect on headache after spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA 1-2; aged 20 to 35 years; patient satisfaction; no history of cardiovascular disease; avoiding the use of selective serotonin reuptake inhibitors and opioids; non preeclampsia and eclampsia; no history of migraine; body mass index less 30
exclusion criteria: history of cardiovascular disease; migraine headaches; use of selective serotonin reuptake inhibitors; ondansetron and sensitivity to local anesthetics and contraindications of spinal anesthesia; the patient's lack of cooperation; piercing the dura more than once; the need to serve an incomplete spinal anesthesia drugs

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Dr Mohammad Rafiei, Vice chancellor for research,
Payambar azam complex, Basij square, Sardasht,
Arak

City

Arak

Postal code

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

ir.arakmu.rec.1394.274

Health conditions studied

1

Description of health condition studied

Post spinal Punctur Headache

ICD-10 code

O89.5

ICD-10 code description

Other complications of spinal and epidural anaesthesia during the puerperium

Primary outcomes

1

Description

Headache

Timepoint

24 Hour, 48 Hour, 4 Day, 7Day

Method of measurement

Mild, Moderate, Severe Based on Standard questionnaires

2

Description

Nausea

Timepoint

24 Hour, 48 Hour, 4 Day, 7Day

Method of measurement

Based on the score of specified ago

3

Description

Vomitting

Timepoint

24 Hour, 48 Hour, 4 Day, 7Day

Method of measurement

Based on the score of specified ago

Secondary outcomes

1

Description

blood pressure

Timepoint

Every 5 minutes to 30 minutes after spinal anesthesia

Method of measurement

By strain gauges attached to the monitor

2

Description

heart beat

Timepoint

Every 5 minutes to 30 minutes after spinal anesthesia

Method of measurement

By pulse oximeter attached to the monitor

Intervention groups

1

Description

Group II: 4 mg of ondansetron with its volume to 5 ml of normal saline has to be encoded and then intravenously 5 minutes before the operation.

Category

Treatment - Drugs

2

Description

Group III: 5 mL of saline for 5 minutes before surgery is encoded and then administered intravenously.

Category

Treatment - Drugs

3

Description

Group I: ondansetron 8 mg with 5 ml of normal saline to have its volume is then encoded and intravenously administered 5 minutes before the operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital in Arak

Full name of responsible person

Dr Alireza Kamali

Street address

Taleghani Hospital, Emam Khomeini street

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafie

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

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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

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 Hesamodin Modir

Position

Faculty member, Anesthesiologist

Other areas of specialty/work

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Faculty member, Anesthesiologist

Other areas of specialty/work

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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