Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 an 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 ondancetron 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
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
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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr Marzieh Shahidani

Position

resident of anesthesiology

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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