Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Survey the effect of ondansetron on the postoperative headache in parturients undergoing cesarean section under spinal anesthesia.

Protocol summary

Summary

The aim of this study is evaluation of the effect of ondansetron on decreasing the incidence of PDPH and related effects of ondansetron on nausea and vomiting, blood pressure and heart rate. Two hundred and ten parturients who will undergo elective cesarean section under spinal anesthesia randomly will be allocated into two groups, in the intervention group, parturients will be received 0.15 mg/kg ondansetron in total volume of 2 ml. while, in the control group, parturients will be received 2ml normal saline. Heart rate, mean arterial pressure during surgery will be recorded. Incidence of nausea and vomiting and post operative headache will be followed by anesthesia nurses for 3 days in both groups and will be compared to each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092111662N3**
Registration date: **2013-11-04, 1392/08/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-11-04, 1392/08/13

Registrant information

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Name of organization / entity

Shiraz University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

Expected recruitment start date

2013-11-23, 1392/09/02

Expected recruitment end date

2014-05-23, 1393/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of ondansetron on the postoperative headache in parturients undergoing cesarean section under spinal anesthesia.

Public title

The effects of ondansetron on reduction of the incidence of post spinal headache in parturients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclision Criteria: parturients who will candidate for elective cesarean section under spinal anesthesia .
Exclusion criteria: parturients with the history of cardiovascular disorder; taking antimigraine medications or selective serotonin reuptake inhibitors; hypersensitivity to ondansetron and local anesthetic drugs; those who have contraindication to do spinal anesthesia .

Age

From **20 years** old to **40 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

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University Medical Research Ethic Committee
Street address
Shiraz University of Medical Sciences ,Zand Blv
City
Shiraz
Postal code
197871345
Approval date
2013-09-22, 1392/06/31
Ethics committee reference number
CT-92-162

Health conditions studied

1

Description of health condition studied
Post dural puncture headach
ICD-10 code
029
ICD-10 code description
Spinal and epidural anaesthesia-induced headache during pregnancy

Primary outcomes

1

Description
Incidence of postdural puncture headach
Timepoint
1st day postoperation, 2nd day post operation, 3rd day postoperation.
Method of measurement
Clinical observation

Secondary outcomes

1

Description
Incidence of the nausea and vomiting
Timepoint
During surgery, 1st day postoperation
Method of measurement
Clinical observation

2

Description
Blood pressure and hear rate
Timepoint
Every 15 minutes during surgery
Method of measurement
Blood pressure: by sphygmomanomete, Heart rate : by electrocardiogram.

Intervention groups

1

Description
In the group O, before spinal anesthesia , parturients will be received intravenous (i.v) ondansetron 0.15 mg/kg diluted in 5 ml of normal saline .
Category
Treatment - Drugs

2

Description
In the control group parturients will be received 5 ml ormal saline before spinal anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zainab Training and Medical Center
Full name of responsible person
Mohammad Ali Sahmeddini
Street address
Hazrat Zainab Training and Medical Center,Holy Defence Sq
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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery of Research and Technology
Full name of responsible person
Dr.Gholamreza Hatam
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Vice-Chancellery of Research and Technology Department, 7th floor,Shiraz University Of Medical Sciences building
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellery of Research and Technology
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

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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