Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of oral and intravenous ondansetron in the prevention of postoperative nausea and vomiting in cesarean section with spinal anesthesia

Protocol summary

Summary

Purpose: The purpose of this study is to Compare of oral and intravenous ondansetron in the prevention of postoperative nausea and vomiting in cesarean section with spinal anaesthesia.Plan: This is a randomized, double-blind, with placebo and clinical trial phase II study.Inclusion criterion: patients who were candidates for cesarean section with spinal anaesthesia.Exclusion criteria: patients who had more than two failure in spinal anaesthesia and had a history of postoperative nausea and vomiting, history of motion sickness, history of allergy to ondansetron, history of hyperemesis gravidarum. The sample size in this study is 162.Interventions: all patients underwent spinal anesthesia and patient in group one recived 8 mg(two tablet) ondansetron orallry 30 minutes before surgery and recived 2 ml Distilled water intravenously after spinal anesthesia, in group two recived two tablets as same as ondansetron 30 minutes before surgery and recived intravenous 4 mg (2 cc) ondansetron after spinal anesthesia and in group three recived two tablets as same as ondansetron 30 minutes before surgery and recived 2 ml Distilled water intravenously after spinal anesthesia.Primary outcome:in 0,1,2,4,6 hours after arrive to recovery "nausea and vomiting" and " level of consciousness" were recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212162080N13**
Registration date: **2013-06-19, 1392/03/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-19, 1392/03/29

Registrant information

Name

Afsaneh Norouzi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences,Vice chancellor for research

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-06-18, 1392/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral and intravenous ondansetron in the prevention of postoperative nausea and vomiting in cesarean section with spinal anesthesia

Public title

Comparison of oral and intravenous ondansetron in the prevention of postoperative nausea and vomiting in

cesarean section with spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-45 and ASA Class I and II Exclusion criteria: history of postoperative nausea and vomiting; history of motion sickness; history of allergy to ondansetron; more than two failure in spinal anaesthesia; history of hyperemesis gravidarum.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **162**

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

Ethical Committee of Arak University of Medical Sciences

Street address

Alamolhoda Ave, Arak University of Medical Sciences

City

arak

Postal code

Approval date

2012-11-26, 1391/09/06

Ethics committee reference number

91-137-2

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

At 0, 1, 2, 4 and 6 hours after arrive to recovery

Method of measurement

Clinical assesment

2

Description

Consciousness

Timepoint

At 0, 1, 2, 4 and 6 hours after arrive to recovery

Method of measurement

Using Ramsay score

Secondary outcomes

empty

Intervention groups

1

Description

In group one, patients recived 8 mg(two tablet) ondansetron orallry 30 minutes before surgery and recived 2 ml Distilled water intravenously after spinal anaesthesia

Category

Prevention

2

Description

In group two, patients recived two tablets as same as ondansetron 30 minutes before surgery and recived intravenous 4 mg (2 cc) ondansetron after spinal anaesthesia

Category

Prevention

3

Description

In group three, patients recived two tablets as same as ondansetron 30 minutes before surgery and recived 2 ml Distilled water intravenously after spinal anaesthesia

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Talghani hospital
Full name of responsible person
Street address
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 Science, Basij Square
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

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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