Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effect of intravenous ondansetron in preventing hypotension in elective cesarean patients under spinal Anesthesia

Protocol summary

Summary

This clinical trial research has been planned to study intravenous ondansetron effect on the prevention of blood pressure decrease after spinal anesthesia in elective cesarean section patients. 102 healthy pregnant women under spinal anesthesia receive hyperbaric bupivacaine (0.5%) in addition sufentanil (5micro gram) after ringer serum infusion (300cc). Before anesthesia, ondansetron 4mg/IV inject slowly, for case group. For control group placebo is injected. The first consequence is hypotension (SBP <100 mmhg or decrease >20% primary BP). Blood pressure and pulse rate are recorded before and after anesthesia immediately, then every 3min till 10min and every 5min till 30min. If hypotension happens, ephedrine 5_10mg will be injected. Itching and nausea will be recorded every 10min during operation by observation and Question. Scoring: Itching 0: no 1: mild 2: severe (need to treat) Nausea 0: no 1: yes. In both of groups, the effect of ondansetron will be studied in hypotension accuracy, bradycardia, consumed ephedrine amount, itching and nausea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111138090N1**
Registration date: **2012-02-28, 1390/12/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-28, 1390/12/09

Registrant information

Name

Bita Malekianzadeh

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1835 0609

Email address

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2010-08-24, 1389/06/02

Expected recruitment end date

2011-07-21, 1390/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous ondansetron in preventing hypotension in elective cesarean patients under spinal Anesthesia

Public title

Ondansetron effect in cesarean

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant healthy women who are candidate for elective cesarean section with spinal anesthesia. Exclusion criteria: motion sickness; hypertension; weight greater than 100kg; hepatic disease; migraine; allergy to ondansetron group drugs, using drugs that effect blood pressure or heart rate or serotonin receptor.

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: **102**
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
Hamedan University of Medical Sciences
Street address
Hamedan University of Medical Sciences, Shahid Fahmideh Boulevard
City
Hamedan
Postal code
Approval date
2011-02-27, 1389/12/08
Ethics committee reference number
16/70/7/183954/پ

Health conditions studied

1

Description of health condition studied
Spinal anesthesia
ICD-10 code
O29.5
ICD-10 code description
Other complications of spinal and epidural anaesthesia during pregnancy

Primary outcomes

1

Description
Bradycardia
Timepoint
Every 3 min till 10 min after anesthesia then every 5 min
Method of measurement
Heart rate per minute, automatic monitoring

2

Description
Hypotension
Timepoint
Every 3min till 10min after anesthesia, then every 5min till minute 30
Method of measurement
mmHg, automatic

Secondary outcomes

1

Description
Itching
Timepoint
Every 10 minute after anesthesia till minute 30
Method of measurement
Question from patient, scoring: 0 no- 1 mild- 2 severe (need to treat)

2

Description
Nausea and vomiting
Timepoint
Every 10 minute after anesthesia till minute 30
Method of measurement
Question from patient, scoring: 0 no- 1 yes.

3

Description
Mean consumed ephedrine
Timepoint
After anesthesia until end of operation
Method of measurement
Milligram

Intervention groups

1

Description
Case group: 4 mg (2cc) ondansetron IV inject Slowly before spinal anesthesia.
Category
Prevention

2

Description
Control group: 2cc sterile water IV injection before spinal anesthesia.
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital

Full name of responsible person
Bita Malekianzadeh, Anesthesia resident

Street address
Shariati Square

City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research vice Chancellorship, Hamedan University of Medical Sciences

Full name of responsible person
Dr. Puran Hajian

Street address
Hamedan University of Medical Science Research vice Chancellorship, Shahid Fahmideh boulevard

City
Hamedan

Grant name

Grant code / Reference number

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

Title of funding source
Research vice Chancellorship, Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Dr. Bita Malekianzadeh

Position
Anesthesia resident

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