Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Ondansetrone for prevention of shivering during and after cesarean with spinal anesthesia

Protocol summary

Summary

Shivering is one of the most common intra and postoperative problems with a 20%-60% reported incidence. In addition to patient's discomfort, intra and postoperative hypothermia and shivering interfere with patent's monitoring and can increase oxygen consumption andCO2production. Recently serotonin receptor antagonists have been shown to be effective in the prevention of intra and postoperative shivering. The aim of this study is to evaluate the effect of Ondansetron in prevention of shivering in patients undergoing to cesarean section with spinal anesthesia with suggestion that prophylactic administration of this agent can prevent inta and postoperative shivering or reduce its severity. After obtaining written informed consent for entering to study, one hundred pregnant patients scheduled for cesarean section, will be enrolled in two groups of 50 and received spinal anesthesia. Case or ondansetron group will be administered 4 mg ondansetron immediately after delivery and cord clamping and the control group will receive normal saline as placebo in the same volume (2 cc). The incidence and severity of inta and postoperative shivering will be checked and recorded according to Crossley and Mahjon scores. Shivering scores equal to or higher than 3 will be treated with 0.5 mg/kg IV Meperidine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020911700N6**
Registration date: **2015-06-29, 1394/04/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-29, 1394/04/08

Registrant information

Name
Farnaz Moslemi Tabrizi
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Alzahra hospital, Tabriz university of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2016-03-01, 1394/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ondansetrone for prevention of shivering during and after cesarean with spinal anesthesia

Public title

The effect of prophylactic administration of intravenous Ondansetron for control of shivering during and after spinal anesthesia for cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Pregnant women candidate for elective cesarean section with spinal anesthesia; ASA physical class I or II with informed consent for spinal anesthesia Exclusion criteria:Patients with ASA physical class III or higher;preexisting cardiovascular diseases; respiratory diseases; preeclampsia or any hypetensive disorders during pregnancy;fever; any contraindication for performing spinal anesthesia

Age
From **18 years** old to **44 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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 of Vice chancellor for Research,Tabriz University Of Medical Sciences

Street address
Vice chancellor for Research,No.2 central building of Tabriz University Of Medical Sciences,Golgasht ave

City
Tabriz

Postal code
5138665793

Approval date
2015-01-12, 1393/10/22

Ethics committee reference number
93156

Health conditions studied

1

Description of health condition studied
Intra and post spinal anesthesia shivering

ICD-10 code
R68.0

ICD-10 code description
Hypothermia, not associated with low environmental temperature

2

Description of health condition studied
complications of anaesthesia

ICD-10 code
T88.5

ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
Incidence of intra and postoperative shivering

Timepoint
during surgery and in recovery

Method of measurement
Observation

2

Description
Severity of intra and postoperative shivering

Timepoint
during surgery and in recovery

Method of measurement
Crossly and Mahjon five-point scoring system

Secondary outcomes

1

Description
need for rescue tyreatment of shivering

Timepoint
during surgery and in recovery

Method of measurement
observation

Intervention groups

1

Description
Intervention:In this group ondansetron 4 mg iv and total volume of 2 ml was administered after neonatal delivery and clamping of the cord for prevention of intra and post-operative shivering .

Category
Prevention

2

Description
control group:In this group normal saline iv in total volume of 2 ml was administered as placebo after

neonatal delivery and clamping of the cord .

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

AlzahraTeaching Hospital ,Tabriz University of Medical Sciences

Full name of responsible person

Dr Farnaz Moslemi

Street address

Alzahra Teaching Hospital, South Artesh ave.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University Of Medical Sciences

Full name of responsible person

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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

Vice chancellor for Research, Tabriz 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

Research Center,Tabtiz University Of Medical Sciences

Full name of responsible person

Farnaz Moslemi

Position

Associated professore of Anesthesia,Anesthesiology

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