

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2015-06-29, 1394/04/08

#### 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 patient's monitoring and can increase oxygen consumption and CO<sub>2</sub> production. 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 intra 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 intra 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

#### Registrant information

##### Name

Farnaz Moslemi Tabrizi

##### Name of organization / entity

Alzahra hospital, Tabriz university of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1553 9161

##### Email address

moslemif@tbzmed.ac.ir

#### 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 Ondansetron 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 hypertensive 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 treatment 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 postoperative 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

Dr Farnaz Moslemi

##### Street address

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

##### City

Tabriz

##### 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

##### Street address

Alzahra Hospital, Artesh Ave, Tabriz

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##### Phone

+98 41 3553 9161

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moslemifa@gmail.com

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Reaserch Center , Tabriz University of Medical Sciences

##### Full name of responsible person

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Research Center, Tabriz University of Medical Sciences

##### Full name of responsible person

Farnaz Moslemi

##### Position

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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*