

# 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

##### Name

Mohammad Ali Sahmeddini

##### Name of organization / entity

Shiraz University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1231 8072

##### Email address

sahmeddini@sums.ac.ir

##### 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

Inclusion 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

##### City

Shiraz

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice-Chancellery of Research and Technology

**Full name of responsible person**

Dr.Gholamreza Hatam

**Street address**

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

**Contact****Name of organization / entity**

Shiraz University Of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahmeddini

**Position**

Associate Professor of Anesthesiology

**Other areas of specialty/work****Street address**

Shiraz Anesthesiology and Critical Care Center,  
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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

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### Person responsible for updating data

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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*