

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison prophylactic effect of Ondansetron and Dexamethasone in management post- dural puncture headache (PDPH) in women candidated for elective Cesarean

#### Protocol summary

##### Study aim

The main objective of this study is comparing the efficacy of ondansetron and dexamethasone in controlling headaches associated with spinal anesthesia in non-emergent candidates for cesarean-section.

##### Design

120 women candidates for cesarean-section in Taleghani hospital in Arak city will be enrolled in the study and equally be divided to three groups randomly by random number table . This study is clinical trial and double blind.

##### Settings and conduct

This study is a clinical trial and double blind that will be done in Taleghani hospital in Arak city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Elective repeated (second) cesarean section; candidate for cesarean with spinal anesthesia Exclusion criteria: lack of consent; candidate cesarean with general anesthesia; drug allergy; emergency cesarean section

##### Intervention groups

120 c-section candidates will be enrolled in the study and equally will be divided to three groups. Study groups 1, 2 and 3 will receive intravenous ondansetron, intravenous dexamethasone, and intravenous distilled water (placebo).

##### Main outcome variables

Headache intensity at 12, 24, and 48 hours post-operative via the visual analogue scale.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170802035464N2**  
Registration date: **2018-07-04, 1397/04/13**

Registration timing: **retrospective**

Last update: **2018-07-04, 1397/04/13**

Update count: **0**

##### Registration date

2018-07-04, 1397/04/13

##### Registrant information

###### Name

Shakiba Homayooni

###### Name of organization / entity

Medicine Student Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3313 6055

###### Email address

homayoni.sh@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor research, Arak University of Medical Sciences

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison prophylactic effect of Ondansetron and Dexamethasone in management post- dural puncture

headache (PDPH) in women candidated for elective  
Cesarean

**Public title**  
A clinical trial comparing the preventive effect of  
Ondansetron and Dexamethasone on control of  
headache caused by local anesthetic from the lumbar in  
non-emergency cesarean section

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Informed consent Elective repeated (second) cesarean  
section Candidate cesarean with spinal anesthesia  
**Exclusion criteria:**  
Lack of consent Candidate cesarean with general  
anesthesia Drug allergy Emergency cesarean section

**Age**  
From **17 years** old to **17 years** old

**Gender**  
Female

**Phase**  
2-3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Table of random numbers

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Evaluator, and data analyzer will not be aware of the  
groups. Only the person who makes the medications  
knows each group and its samples. the person who  
evaluates the outcome and analyzer are unaware of the  
medication given to each group.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**  
clinical trial and double blind

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Arak University Of Medical Sciences

##### Street address

Arak University Of Medical Sciences

##### City

Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Approval date**  
2016-12-12, 1395/09/22  
**Ethics committee reference number**  
IR.ARAKMU.MU.REC.1395.314

## Health conditions studied

### 1

#### Description of health condition studied

elective cesarean section

#### ICD-10 code

O82.0

#### ICD-10 code description

Delivery by elective caesarean section

## Primary outcomes

### 1

#### Description

headache

#### Timepoint

12, 24 and 48 hours after cesarean

#### Method of measurement

Visual Analogue Scale of pain

## Secondary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Every 15 minute until end of recovery

#### Method of measurement

Sphygmomanometer (millimeter Hg)

### 2

#### Description

Heart rate

#### Timepoint

Every 15 minute until end of recovery

#### Method of measurement

Beat in minute

## Intervention groups

### 1

#### Description

We inject 8 milligram Dexamethasone slow  
intravenously.

#### Category

Prevention

## 2

### Description

We inject 8 milligram Ondansetron slow intravenously.

### Category

Prevention

## 3

### Description

We inject 8 milligram distilled water as placebo intravenously.

### Category

Prevention

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Taleghani Hospital

#### Full name of responsible person

Dr Maryam Shokrpour

#### Street address

Arak

#### City

Arak

#### Province

Markazi

#### Postal code

3814957558

#### Phone

+98 86 3222 2003

#### Fax

+98 86 3222 2003

#### Email

m.shokrpour@arakmu.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr Anoshirvani

#### Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

#### City

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#### Postal code

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#### Phone

+98 86 3417 3645

#### Fax

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#### Email

Anoshirvani@arakmu.ac.ir

### 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

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr Alireza Kamali

#### Position

Assistant professor, Anesthesiologist

#### Latest degree

Specialist

#### Other areas of specialty/work

Anesthesiology

#### Street address

Shahid Shirodi street, Valiasr square, Valiasr hospital

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#### Email

alikamaliir@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr Maryam Shokrpour

#### Position

Assistant professor, gynecologist

#### Latest degree

Specialist

#### Other areas of specialty/work

Gynecology and Obstetrics

**Street address**

Taleghani Hospital, Emam Khomeini Street, Arak

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

When we publish article in journal

**When the data will become available and for how long**

After the article is published

**To whom data/document is available**

researcher in university

**Under which criteria data/document could be used**

If there are additional questions

**From where data/document is obtainable**

Dr Alireza Kamali

**What processes are involved for a request to access data/document**

They have to write letters to the professors and the university

**Comments**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Shakiba Homayooni

**Position**

Medicine Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Complex Payambar azam, Basij square, Sardasht, Arak

**City**

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**Province**

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**Postal code**

3814957558

**Phone**