

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3417 3645

Fax

+98 86 3417 3645

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

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikalaliir@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

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikalaliir@yahoo.com

Web page address

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

homayoni.sh@arakmu.ac.ir

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

Arak

Province

Markazi

Postal code

3814957558

Phone