

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A Comparison Review of The Effects of Dexamethasone and Ondansetron Intravenous on Preventing Headache after Spinal Sedation of Patients under a Cesrean Section.

Protocol summary

Summary

The aim of this study was to evaluate the effect of dexamethasone and endonestrone on patients in three different groups. Inclusion criteria include gender, pregnancy, cesarean section and exit criteria including headache, nausea and vomiting. The study volume was 150 people. The intervention has an effect on the dexamethasone, andandonestrone and placebo exposure to the studied groups before and after the time of spinal anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022532768N1**
Registration date: **2017-11-19, 1396/08/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Mozhdeh Ghaffari

Name of organization / entity

Islamic Azad University of Ardabil

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 8020

Email address

mozhdeh.ghaffari70@gmail.com

Recruitment status

Recruitment complete

Funding source

Deputy of Research of Islamic Azad University

Expected recruitment start date

2000-01-01, 1378/10/11

Expected recruitment end date

2008-01-01, 1386/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison Review of The Effects of Dexamethasone and Ondansetron Intravenous on Preventing Headache after Spinal Sedation of Patients under a Cesrean Section.

Public title

A Comparison of The Effects of Dexamethasone and Ondansetron Intravenous on Preventing Headache of Patients Under a Cesarean Section

Purpose

Prevention

Inclusion/Exclusion criteria

Entry criteria: Female: Pregnant: Satisfaction for drug injection Exit criteria: Migraine disease: history of headache

Age

From **1 year** old to **1 year** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

The Ethics Committee of Islamic Azad University of Ardebil

Street address

No 342, Ardabil University of Medical Sciences,
Ayatollah Moghadas Ardebi St, Shahid Moadi Ave,
Ardabi, IRAN

City

Ardabil

Postal code

5615731567

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.IAU.ARDABIL.REC.1395.19

Health conditions studied

1

Description of health condition studied

Delivery with Cesarean Section

ICD-10 code

O82.9

ICD-10 code description

Delivery by Caesarean Section, Unspecified

2

Description of health condition studied

Headache Caused by Spinal / Epidural Anesthesia

ICD-10 code

O74.5

ICD-10 code description

Spinal and Epidural Anaesthesia-Induced Headache
During Labour and Delivery

Primary outcomes

1

Description

headache

Timepoint

Before and after the spinal anesthesia

Method of measurement

questionnaire

2

Description

nausea

Timepoint

Before and after the spinal anesthesia

Method of measurement

questionnaire

3

Description

vomit

Timepoint

Before and after the spinal anesthesia

Method of measurement

questionnaire

Secondary outcomes

1

Description

bradycardia

Timepoint

Before and after the spinal anesthesia

Method of measurement

ECG device

2

Description

hypotention

Timepoint

Before and after the spinal anesthesia

Method of measurement

barometer

3

Description

headach

Timepoint

Before the spinal anesthesia

Method of measurement

questionnaire

4

Description

nausea

Timepoint

Before the spinal anesthesia
Method of measurement
questionnaire

Intervention groups

1

Description
dexamethason,8 mg,IV,befor spinal anesthesia
Category
Prevention

2

Description
ondansetron,4 mg,IV,befor spinal anesthesia
Category
Prevention

3

Description
Control group: No special drug injection
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi Hospital
Full name of responsible person
Mozhdeh Ghafari
Street address
No 6, Ayatollah Moghadas Ardebi St, , Shahid Moadi Ave, Ardabi, IRAN
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research of Islamic Azad University
Full name of responsible person
Masood Fardin
Street address
No 342, Ardabil University of Medical Sciences, AyatollahMoghadas Ardebi St, Shahid Moadi Ave, Ardabi, IRAN
City
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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
Deputy of Research of Islamic Azad University
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
Islamic Azad University of Ardabil Branch
Full name of responsible person
Mozhdeh Ghaffari
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Medical Student
Other areas of specialty/work
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Full name of responsible person

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

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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