

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A clinical trial comparing administration versus non-administration of intravenous Dexamethasone on the incidence of headache after spinal anesthesia in women undergoing caesarean section

Protocol summary

Summary

This randomized, double-blind clinical trial examined the effects of intravenous dexamethasone on the incidence of headache after spinal anesthesia in candidates of cesarean section. This study is in the second phase of clinical trials and was conducted on 104 patients. The inclusion criteria consisted of age from 15 to 45 years; pregnant women of Class 1 and 2 with uncomplicated term pregnancy according to the physical status classification by the American Society of Anesthesiologists; and candidature for cesarean section. The study was performed in Valiasr Hospital of Birjand. All the patients underwent spinal anesthesia using quince 25 needle with 0.5 percent 12-15 milligram bupivacaine (topical anesthetic). After spinal anesthesia, the patients were allocated into control and intervention groups (n= 52 per group) via simple random allocation method. In the intervention group, 8 milligram intravenous dexamethasone was injected. In the control group, 2 cc distilled water or normal saline was injected. Forty-eight hours after the operation, the severity of headache was studied and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080117756N22**
Registration date: **2017-08-30, 1396/06/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-30, 1396/06/08

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research, Birjand University of Medical Sciences

Expected recruitment start date

2013-08-16, 1392/05/25

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing administration versus non-administration of intravenous Dexamethasone on the incidence of headache after spinal anesthesia in women undergoing caesarean section

Public title

The effects of intravenous Dexamethasone on headache

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age from 15 to 45 years; pregnant

woman of Class 1 and 2 with uncomplicated term pregnancy according to the physical status classification by the American Society of Anesthesiologists; candidature for cesarean section surgery. Exclusion criteria: Prohibition of spinal anesthesia (for example, coagulation disorders, peripheral neuropathy, infection of the needle insertion site, and spinal cord disorders); history of headache, migraine, and hypertension (as in eclampsia and preeclampsia).

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Both the data collectors and the patients were uninformed of the allocated groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice-chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand,

Postal code

Approval date

2013-08-12, 1392/05/21

Ethics committee reference number

lr.bums.1394.403

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

O89.4

ICD-10 code description

Spinal and epidural anaesthesia-induced headache during the puerperium

Primary outcomes

1

Description

Headache severity

Timepoint

48 hours after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control Group (distilled water or normal saline): All the patients underwent spinal anesthesia using quince 25 needle with 0.5 percent 12-15 milligram bupivacaine (topical anesthetic). Then, 2 cc distilled water or normal saline was injected.

Category

Prevention

2

Description

Intervention Group (intravenous dexamethasone): All the patients underwent spinal anesthesia using quince 25 needle with 0.5 percent 12-15 milligram bupivacaine (topical anesthetic). Afterwards, 8 milligram intravenous dexamethasone was injected intravenously after spinal anesthesia.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr. Bibi Fatemeh Shakhs Emampour

Street address

Ghafari Street,

City

Birjand,

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery for Research and Technology of
Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

Street address

Vice-chancellor for Research, Birjand University of
Medical Sciences, Ayatollah Ghafari Street,

City

Birjand,

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-Chancellery for Research and Technology of Birjand
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**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Bibi Fatemeh Shakhs Emampour

Position

Anesthesiologist

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Position

Assistant Professor of Anesthesiology

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Full name of responsible person

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Position

PhD Candidate in Translation Studies

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Web page address

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