Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity

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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
Ir.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

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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