Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

study of the prophylactic effect of Dexamethasone on the headache after spinal anesthesia in patients undergoing cesarean

Protocol summary

Summary

The purpose of this study was to evaluate the prophylactic effect of Dexamethasone in the prevention of headache after spinal anesthesia in patients undergoing cesarean. This study is a double blind clinical trial. 100 patients who have undergone caesarean electively or in an emergency were divided randomly into intervention and control groups. Spinal puncture was performed in all patients with Marcaine drug in a sitting position at L4-L5 through spinal needle 25 Whitaker. Patients in the intervention group took 0.15 mg dexamethasone intravenous per each kilogram of body weight immediately after cord clamping. At 24 hours and 7 days after, they were asked about the headache and compared with control group which received normal saline as placebo. Inclusion criteria: patients aged 20 to 35; 150 to 170 cm in height; included in the ASA Class I and II and those signed a written consent. Exclusion criteria: All patients who were not included in ASA class I and II; patients didn’t sign the written consent; to have an underlying disease; complaining about any acute or chronic headache before spinal punctures; to use any analgesic drugs in the last two days; any contraindication to spinal anesthesia; to have a history of kidney, heart and lung diseases, or drug allergy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090314333N7**
Registration date: **2013-10-12, 1392/07/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-10-12, 1392/07/20

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Kermanshah University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study of the prophylactic effect of Dexamethasone on the headache after spinal anesthesia in patients undergoing cesarean

Public title

study of the prophylactic effect of Dexamethasone on the headache after spinal anesthesia in patients undergoing cesarean

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 20 to 35; 150 to 170 cm in height; included in the ASA Class I and II and those

signed a written consent. Exclusion criteria: All patients who were not included in ASA class I and II; patients didn’t sign the written consent; to have an underlying disease; complaining about any acute or chronic headache before spinal punctures; to use any analgesic drugs in the last two days; any contraindication to spinal anesthesia; to have a history of kidney, heart and lung diseases, or drug allergy.

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2013-01-16, 1391/10/27

Ethics committee reference number
48670/7/420/پ

Health conditions studied

1

Description of health condition studied
Headache after spinal anesthesia

ICD-10 code
O29.4

ICD-10 code description
Spinal and epidural anaesthesia-induced headache during pregnancy

Primary outcomes

1

Description
headache

Timepoint
24 hours and seven days after surgery

Method of measurement
Asking the patients(mild,medium,high)

Secondary outcomes

empty

Intervention groups

1

Description
0.15 mg Dexamethasone intravenous(per each kilogram of body weight) is prescribed to the intervention group immediately after cord clamping

Category
Treatment - Drugs

2

Description
intravenous normal saline is prescribed to the control group immediately after cord clamping

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Dr. Mohamad Nematizade

Street address
Emam Reza Hospital,Razi Boulvard,Sorkhleje

City
Kermanshah

2

Recruitment center

Name of recruitment center
Motazedi Hospital

Full name of responsible person
Dr.Mohamad Nematizade

Street address
Ferdosi Square,Motazedi Hospital

City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
Full name of responsible person
koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research Affairs, Kermanshah 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Parisa Golfam
Position
Anesthisiologist
Other areas of specialty/work
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Emam Reza Hospital,Razi Boulvard,Sorkhleje
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Kermanshah
Postal code
Phone
+98 83 1427 6309
Fax
Email
pgolfam@kums.ac.ir
Web page address

Person responsible for updating data

Contact

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