

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

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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 Boulevard,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
Anesthesiologist
Other areas of specialty/work
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Emam Reza Hospital,Razi Boulevard,Sorkhleje
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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