

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of dexamethasone on incidence of headache and backache after spinal anesthesia in cesarean section

Protocol summary

Summary

This study is a parallel randomized single-blind clinical trial. It was performed during 12 months in 1390 in 22 Bahman hospital in Gonabad on 160 candidates of cesarean section with spinal anesthesia. For all subjects using anesthesia was sitting position and location of the L3-L4, L4-L5 with a disposable 25-gauge needle with 75 mg lidocaine 5% and 25 mcg of fentanyl. Headache and backache in the first 24 hours and first week after spinal anesthesia were checked. A BSc of Anesthesia filled out the questionnaire. Inclusion criteria were willing to participate in the study, age between 20-40 years, having in cesarean section under spinal anesthesia, physical status be class I and II according to ASA, no history of psychological disease and no history of migraine or backache. Anesthesia or other surgery during the study were the exclusion criteria. For blindness the person who examines and the questioner were not aware of the administration of dexamethasone during spinal anesthesia. Subjects randomly classified into two groups: Intervention group (spinal anesthesia in a sitting position, needle No. 25, with 75 mg lidocaine 5% and 25 micrograms fentanyl and dexamethasone 8 mg intravenous infusion during spinal anesthesia) and Control group (spinal anesthesia in a sitting position, needle No. 25, with 75 mg lidocaine 5% and 25 mcg fentanyl).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201095445N2**

Registration date: **2012-05-23, 1391/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-23, 1391/03/03

Registrant information

Name

Arash Hamzei

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 53 3722 3028

Email address

arash_hamzei@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Gonabad University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-18, 1390/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dexamethasone on incidence of headache and backache after spinal anesthesia in cesarean section

Public title

Effect of dexamethasone on incidence of headache and backache after spinal anesthesia in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: To be ready to join in trial; age between 20 - 40 years; cesarean section under spinal anesthesia; physical status be class I and EI according to ASA; no history of psychological disease; no history of migraine or backache. Exclusion criteria: Another anesthesia or any other surgery during the week of study.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Dr Mehdizade street, Medical University Campus, Gonabad

City

Gonabad

Postal code

9691793718

Approval date

2011-12-10, 1390/09/19

Ethics committee reference number

6/3/90

Health conditions studied

1

Description of health condition studied

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

First 24 hours and first week

Method of measurement

Questionnaire

2

Description

Backache

Timepoint

First 24 hours and first week

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control Group: anesthesia was in sitting position and location of the L3-L4, L4-L5 with a disposable 25-gauge needle with 75 mg lidocaine 5% and 25 mcg of fentanyl.

Category

Treatment - Drugs

2

Description

Intervention group: intraoperative injection of intravenous dexamethasone 8mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital, Gonabad

Full name of responsible person

Dr Arash Hamzei, Anesthesiologist

Street address

Naser Khosro St., Gonabad

City

Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Gonabad University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammadpour

Street address

Dr. Mehdizade Street, Medical University Campus, Gonabad

City

Gonabad

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, Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Arash Hamzei

Position

Anesthesiologist, Assistant Professor

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

22 Bahman Hospital, Naser Khosro St., Gonabad

City

Gonabad

Postal code**Phone**

+98 53 3725 4222

Fax**Email**

arash_hamzei@gmu.ac.ir; arash_hamzei@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr Arash Hamzei

Position

Anesthesiologist, Assistant Professor

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

22 Bahman Hospital, Naser Khosro St., Gonabad

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Gonabad

Postal code**Phone**

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Fax**Email**

arash_hamzei@gmu.ac.ir; arash_hamzei@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr Arash Hamzei

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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