

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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**

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**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**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

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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*