

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Injection of intrathecal normal saline in decreasing postdural puncture headache (PDPH)

Protocol summary

Summary

Purpose: Postdural puncture headache (PDPH) is the most common postoperative complication of spinal anesthesia. The actual mechanism producing the PDPH remains unclear. Numerous studies on its pathophysiology, prevention and treatment have been published. The objective of our study was to evaluate the effect of prophylactic administration of injection of intrathecal normal saline in decreasing postdural puncture headache. Methods: One hundred healthy women (ASA physical status I) with ages between 18-35 years scheduled for elective term cesarean delivery under spinal anesthesia. Subjects were randomly divided into two equal groups. 2.5 ml (12.5 mg) hyperbaric bupivacaine was injected in group C as a control group and the injection of 5mL intrathecal normal saline and then injection of 2.5 mL (12.5 mg) hyperbaric bupivacaine was performed in group S as a study group.

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-04-01, 1388/01/12

Expected recruitment end date

2009-12-31, 1388/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803051951N1**

Registration date: **2011-05-08, 1390/02/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-08, 1390/02/18

Registrant information

Name

Nasrin Faridi Tazeh-kand

Name of organization / entity

Tehran University of Medical Sciences

Country

Scientific title

Injection of intrathecal normal saline in decreasing postdural puncture headache (PDPH)

Public title

Postdural puncture headache and normal saline

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: healthy women (ASA physical status I) with ages between 18-35 years scheduled for elective term cesarean delivery under spinal anesthesia.

Exclusion criteria: Parturient were excluded from the study if they had preexisting hypertension, diabetes mellitus, chronic headache, history of previous PDPH, number of lumbar puncture attempts more than two and contraindication to spinal anesthesia.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 100

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2011-05-01, 1390/02/11

Ethics committee reference number

90/ 210/130/ص

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

existence of headache and severity

Timepoint

12, 24 and 48 hours and 3 rd and 7th days after

cesarean section

Method of measurement
interview

Secondary outcomes

1

Description

complications

Timepoint

any time

Method of measurement

asking patients

Intervention groups

1

Description

After obtaining free-flowing cerebrospinal fluid, the injection of 5mL intrathecal normal saline and then injection of 2.5 mL (12.5 mg) hyperbaric bupivacaine was performed in group S as a study group.

Category

Prevention

2

Description

After obtaining free-flowing cerebrospinal fluid, 2.5 ml (12.5 mg) hyperbaric bupivacaine was injected in group C as a control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women's hospital

Full name of responsible person

Nasrin Faridi Tazeh-kand

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical sciences/Vice chancellor for research

Full name of responsible person

Dr Akbar Fotoohi

Street address

Vice chancellor for research, Tehran University of

Medical sciences
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran University of Medical sciences/Vice chancellor for research
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
 Tehran University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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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