Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Injection of intratechal 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 intratechal 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.

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

Iran (Islamic Republic of)

Phone

+98 21 7788 3283

Email address

nfaridi@sina.tums.ac.ir

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

Scientific title

Injection of intratechal 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 scinces/Vice chancellor for research
Full name of responsible person
Dr Akbar Fotoohi
Street address
Vice chansellor for research, Tehran University of

Medical scinces

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 scinces/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

Dr Nasrin Faridi Tazeh-kand

Position

Associate professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nasrin Faridi Tazeh-kand

Position

Assistant professor

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Scinces

Full name of responsible person

Bita Eslami

Position

Researcher

Other areas of specialty/work

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bita_i2001@yahoo.com

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