

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of “Reverse flow” technique in prevention of post dural puncture headache in cesarean section under spinal anesthesia

Protocol summary

Summary

The aim of this single blinded simple randomized clinical trial is to evaluate of “reverse flow” technique in prevention of headache after dural puncture in cesarean section under spinal anesthesia which performed in Fatemieh hospital. Single blinded trial means that patients don't know whether they are in intervention or control group. After informed consent patients divided into two groups: intervention and control. In simple random sampling we select patients from a large population. Each individual is chosen by chance and each patient has a equal chance of being included in the sample. Each group contains of 120 patients. In intervention group we mix 3 cc marcaine 0.5 % and 1 cc fentanyl and inject 3 cc of this mixture into subarachnoid space by 24 gauge spinal needle then simultaneously with injection of 1 cc of this mixture ,needle is withdrawn. In control group only 3 cc of this mixture inject into subarachnoid space and we have no injection while needle withdrawing. Then we evaluate PDPH at 6, 12, 18, 24, 48, 72 hours after operation and if patient have PDPH we determine severity of pain with Numerical Rating Scale.

General information

Acronym

PDPH: Post Dural Puncture Headache; ASA: American Society of Anesthesiologists;

IRCT registration information

IRCT registration number: **IRCT2015030111822N4**
Registration date: **2015-10-12, 1394/07/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-12, 1394/07/20

Registrant information

Name

Behrooz Karkhanei

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0574

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of Research and Technology, Hamadan University of Medical Science

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of “Reverse flow” technique in prevention of post dural puncture headache in cesarean section under spinal anesthesia

Public title

Evaluation of “Reverse flow” technique in prevention of post dural puncture headache in cesarean section under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Cesarean section; ASA I & II; Exclusion

criteria: patient's refusal; concomitant another surgery; more than 2 time dural puncture in spinal technique; analgesic usage before operation; history of chronic headache; history of PDPH

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **240**

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 University of Medical Sciences

Street address

Hamadan University Of Medical Sciences, Shaheed
Famideh Street

City

Hamadan

Postal code

6517838695

Approval date

2015-03-02, 1393/12/11

Ethics committee reference number

p/16/35/9/6388

Health conditions studied

1

Description of health condition studied

Regional anesthesia

ICD-10 code

O89.4

ICD-10 code description

Spinal and epidural anaesthesia-induced headache during the puerperium

Primary outcomes

1

Description

Severity of headache

Timepoint

6 hours after procedure, 12 hours after procedure, 18 hours after procedure, 24 hours after procedure, second day after procedure, third day after procedure

Method of measurement

Numerical Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group we mix 3 cc marcaine 0.5 % and 1 cc fentanyl and inject 3 cc of this mixture into subarachnoid space by 24 gauge spinal needle then simultaneously with injection of 1 cc of this mixture ,needle is withdrawn.

Category

Prevention

2

Description

In control group only 3 cc of this mixture inject into subarachnoid space and we have no injection while needle withdrawing.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Marjan Lashgary

Street address

Fatemieh Hospital, pasdaran street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Hamadan University of Medical Sciences

Full name of responsible person

Saiid Bashirian

Street address

Vice chancellor of Research and Technology ,
Hamadan University of Medical Sciences, Shaheed
Fahmideh Street

City

Hamadan

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 of Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Behrooz Karkhanei

Position

MD. Assistant Professor of Anesthesiology

Other areas of specialty/work

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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