

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of semi sitting position on Post Dural Puncture Headache in Women undergoing elective Cesarian Section.

Protocol summary

Study aim

Survey the Effect of Head up Position after Spinal Anesthesia, on Incidence of Post Dural Puncture Headache (PDPH).

Design

Randomised, superiority, parallel group trial with blinded outcome assessment. 110 Woman that have Cesarian Section Randomly will be divided in 2 groups; group 1(intervention groupe) recieve Head up position in the Recovery time. and group 2 recieve Supine position at that time. By using Numerical Rating Scale(NRS), We will mesure patient`s post dural punctuer haedache(PDPH) by 5 days after surgery. Data will be collected and studied by Statistical Methods.

Settings and conduct

This study is a randomized double blind clinical trial. In Rafsanjan City and Niknafs Hospital; Womans that have spinal anesthesia for Cesarian Section will participate in the study after Conscious satisfaction. and randomly divided in 2 group; in the recovery time we will using headup position(30 degree) in intervention groupe and head flat position(0 degree) in control groupe. after 5 days we will mesure incidence of Postdural Puncture Headache in each groupe.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Woman by age 19 to 49 years old, ASA Class I, II and Weight from 50 to 85 KG, That have Cesarian Section with Spinal Anesthesia. Exclusion Criteria: history of Druge addiction, history of Migrane and chronic Headache.

Intervention groups

In Intervention groupe; We using Head up position(30 degree) in the end of surgery and in the recovery room. In control groupe; We using flat position of head(0 degree) in the end of the surgery and in the recovery room. We will have one Intervention groupe and one Control groupe.

Main outcome variables

Post Dural Puncture Headache is a positional Headache

in frontal region, that percepts 2 to 5 days after spinal anesthesia. We mesure presense or absence of PDPH , By using Numerical Rating Scale(NRS) 5 days after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181128041788N2**

Registration date: **2019-05-01, 1398/02/11**

Registration timing: **retrospective**

Last update: **2019-05-01, 1398/02/11**

Update count: **0**

Registration date

2019-05-01, 1398/02/11

Registrant information

Name

saeed khorramnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 4014

Email address

dr.khorramnia@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-22, 1397/04/31

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of semi sitting position on Post Dural Puncture Headache in Women undergoing elective Cesarian Section.

Public title

Survey The effect of Position on Post Dural Puncture Headache.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

American Society of Anesthesiologists class I ,II (ASA class I , II). 19 to 49 years old.

Exclusion criteria:

History of Druge Addiction. History of Migrane and Chronic Headache.

Age

From **19 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization Block : We will use Random number table: Couple nunbers will go to intervention group and and Single numbers will go to control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

the Intervener do not follow the results. he will not follow the patients anytime. the Person that Register the results do not know the type of Intervention.he will not know what patient is in what interventional groupe. Thus we use double blind technique.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Science

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717735653

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.RUMS.REC.1397.051

Health conditions studied**1****Description of health condition studied**

Post Dural Puncture Headache

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Post Dural Puncture Headache

Timepoint

5 Days after surgery

Method of measurement

By using Numerical Rating Scale(NRS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Head elevated by 30 degree in the end of surgery and in the Recovery Room.

Category

Prevention

2**Description**

Control group: Head in flat position(elevated 0 degree)in the end of surgery and in the Recovery Room

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Niknafs hospital

Full name of responsible person

saeed khorramnia

Street address

No. 1 Shohada Ave.

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Email

niknafs@rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Shamsyzadeh Ali

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No. 12, Imam Ali Blvd., Aliebn Abitaleb Square.

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alishamsy@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

khorrarnia saeed

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pain subspecialist

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Person responsible for scientific inquiries

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Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of data after unidentification of patients will be shared.

When the data will become available and for how long

6 months after publishing of data.

To whom data/document is available

only for medical institute.

Under which criteria data/document could be used

only for Treatment and for Research cases.

From where data/document is obtainable

by email: saeed.khorramnia@gmail.com

What processes are involved for a request to access data/document

after Registration of request and Confirmation of Institute, the data will send by Email in three months.

Comments