

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 perceptes 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 numbers 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.

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717735941

**Phone**

+98 34 3426 3337

**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

**Street address**

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

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0097

**Fax**

+98 34 3428 0097

**Email**

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**

khorramnia saeed

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pain subspecialist

**Street address**

No. 25, Aboozar Ave.

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717735943

**Phone**

+98 34 3428 4014

**Email**

saeed.khorramnia@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

khorramnia saeed

**Position**

Assistant professor

**Latest degree**

Subspecialist

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## Person responsible for updating data

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**Phone**

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**Email**

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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**