Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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.
City
Rafsanjan
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Postal code
7717735941
Phone
+98 34 3426 3337
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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.
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7717933777
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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
khorramnia saeed
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pain subspecialist
Street address
No. 25, Aboozar Ave.
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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 mounts 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 mounts.
Comments