

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Bilateral Greater Occipital Nerve(GON) block for Treatment of Post Dural Puncture Headache(PDPH) in Cesarian Section.

Protocol summary

Study aim

Survey the Efficacy of Bilateral Greater Occipital Nerve(GON) block for Treatment of Post Dural Puncture Headache(PDPH) after Spinal Anesthesia.

Design

Randomised, superiority, parallel group trial with blinded outcome assessment. 74 woman that have Post Dural Puncture Headache(PDPH) after Cesarian Section Randomly divided in 2 Treatment groups. group 1 recieve Bilateral Greater Occipital (GON)nerve block . and group 2 recieve drug treatment. With using Numerical Rating Scale(NRS) We will mesure patients pain. We do that after 1 hour, 6 hours and 24 hours after interventions. Data will be collected and will studied by Statistical Methods.

Settings and conduct

In Rafsanjan city Patients that have Post Dural Puncture Headache(PDPH) after Cesarian Section, Randomly will be divided in two groups : one group will recieve drug treatment and the other group will recieve Bilateral Greater Occipital nerve(GON) block. this Treatment Methods will evaluate by a person that did not know what kind of Treatment were used . Finally data will be evaluated by Statistical Methods.

Participants/Inclusion and exclusion criteria

All Mothers that have Post Dural Puncture Headache (PDPH) after Cesarian Section.

Intervention groups

Womans with Post Dural Puncture Headache(PDPH) after Cesarian Section that refer to our hospitals for treatment.

Main outcome variables

We will measure Severity of Headache after Treatment by using a Numerical Rating Scales(NRS). Its unit from 0 to 10.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181128041788N1**

Registration date: **2019-01-11, 1397/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-11, 1397/10/21**

Update count: **0**

Registration date

2019-01-11, 1397/10/21

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

2018-01-20, 1396/10/30

Expected recruitment end date

2019-01-19, 1397/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Bilateral Greater Occipital Nerve(GON) block for Treatment of Post Dural Puncture Headache(PDPH) in Cesarian Section.

Public title

Efficacy of Greater Occipital Nerve(GON) block for Treatment of Post Dural Puncture Headache(PDPH).

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All Mothers that have Spinal Anesthesia for Cesarian Section and have Post Dural Puncture Headache(PDPH).

Exclusion criteria:

Truma to Central Nervous System History of Neurologic Headache like Migrane and Tention Headache and etc. Deficiency of Central Nervous System. Pre-eclampcia

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Permuted Blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will not know the type of Treatment, and Evaluator will not know the type of Treatment, too.

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

No. 25, Abuzar Ave.

City

Rafsanjan

Province

Kerman

Postal code

7717735943

Approval date

2018-01-20, 1396/10/30

Ethics committee reference number

IR. RUMS. REC. 1396. 111

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

Post Dural Puncture Headache(PDPH)

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

Post Dural Puncture Headache(PDPH).

Timepoint

1th, 6th, and 24th hours after intervention.

Method of measurement

By using Numerical Rating Scale(NRS).

Secondary outcomes

empty

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

Intervention group: Group that recieve Bilateral Greater Occipital (GON)Nerve Block.

Category

Treatment - Other

2**Description**

Intervention group: Group that recieve Drug Treatment.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Niknafs Hospital

Full name of responsible person

Dr Saeid Khorramnia

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Shohada Ave.

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr Ali Shamsizadeh
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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
Dr saeed khorrarnia
Position
Associate professor of Anesthesiology
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

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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 month after publishing of data

To whom data/document is available

Only for Medical Institute

Under which criteria data/document could be used

for Treatment and for Research causes.

From where data/document is obtainable

saeed.khorramnia@gmail.com

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

After registration of request and confirmation of Institute, we will send the data by email in three months.

Comments