Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Punctuer 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 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
Street address
Shohada Ave.
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2

Recruitment center
Name of recruitment center
Aliebn Abitaleb Hospital
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Dr saeid khorramnia
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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
Street address
No. 10 aliebne abitaleb Ave.
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Email
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Web page address
http://www.rums.ac.ir
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 khorramnia
Position
Associate professor of Anesthesiology
Latest degree
Subspecialist
Other areas of specialty/work
Pain
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Person responsible for updating data

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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 mount 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 mounts.

Comments