Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of greater occipital nerve block in the treatment of medication overuse headache

Protocol summary

Study aim
Evaluation of the effect of greater occipital nerve block in the treatment of medication overuse headache

Design
The current study is an open label, parallel, randomized, controlled clinical trial. Participants who fulfilling the inclusion criteria will be randomized in 1:1 ratio to either group A (n=27) or B (n=27) by permuted blocked randomization.

Settings and conduct
We consecutively evaluated patients with a suspect of medication overuse headache in the Imam Moosa Sadr clinic, Isfahan University of Medical Sciences, Isfahan, Iran. In both group, patients underwent detoxification processes without any analgesics during 3 months. The detoxification is a therapeutic process in which the effects of analgesics in causing medication overuse headache are eliminated. Greater occipital nerve blocks are performed in patients in the intervention group, and the control group will simply undergo the detoxification process without the nerve block.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult patients (aged >18 years), having confirmed diagnosis of medication overuse headache (MOH), previous diagnosis of a primary headache. Exclusion criteria: Psychiatric disorders (e.g. severe depression or schizophrenia), physical disorders (e.g. malignancy, concomitant heart disease), pregnant or lactating.

Intervention groups
In both group, patients underwent detoxification processes without any acute migraine medication or analgesics. Greater occipital nerve blocks are performed in patients in the intervention group, and the control group will simply undergo the detoxification process without the nerve block.

Main outcome variables
Characteristics of headache attacks including headache severity, frequency and duration.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150906023922N2**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **retrospective**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date
2020-07-29, 1399/05/08

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3650 3584
Email address
fkhorvash@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-17, 1398/07/25

Expected recruitment end date
2020-04-03, 1399/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of greater occipital nerve block in

the treatment of medication overuse headache

Public title
Effect of greater occipital nerve block in treatment of headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients (aged >18 years) Having confirmed diagnosis of medication overuse headache (MOH) Previous diagnosis of a primary headache
Exclusion criteria:
Psychiatric disorders (e.g. severe depression or schizophrenia) Physical disorders (e.g. malignancy, concomitant heart disease) Pregnant or lactating
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A blocked randomization method with randomly permuted blocks sizes 4 was used to assign each patients to an intervention or control group, to guarantee recruitment balance between the 2 groups and avoid possible risk for selection bias. Depending on age and gender, individuals are placed in blocks of four and are placed in one of the intervention and control groups using a table of random numbers. Each “block” has a specified number of randomly ordered treatment assignments. Treatment assignments were put in numbered closed envelopes, which were opened sequentially upon patient admission.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjreeb street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-02-02, 1398/11/13
Ethics committee reference number
IR.IAU.YAZD.REC.1398.054

Health conditions studied

1

Description of health condition studied
Medication overuse headache
ICD-10 code
G44
ICD-10 code description
Other headache syndromes

Primary outcomes

1

Description
Headache severity
Timepoint
At baseline and after 12 weeks
Method of measurement
Visual analogue scale

2

Description
Headache frequency
Timepoint
At baseline and after 12 weeks
Method of measurement
Record

3

Description
Headache duration
Timepoint
At baseline and after 12 weeks
Method of measurement
Record

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The greater occipital nerve will be blocked bilaterally using 1 ml of 2% lidocaine and 1 ml of triamcinolone 40 mg / ml. Patients in the intervention group will undergo a detoxification process using complete discontinuation of acute migraine medications or analgesics.

Category

Treatment - Other

2

Description

Control group: No intervention is performed on patients in the control group. Patients in the control group will undergo a detoxification process using complete discontinuation of acute migraine medications or painkillers.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Moosa Sadr clinic
Full name of responsible person
Fariborz Khorvash
Street address
Forooghi Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 1792 2110
Email
fkhorvash@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjou
Street address
Hezarjrib street
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81746-73461
Phone
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sh_haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fariborz Khorvash
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Hezarjarib Ave., Isfahan University of Medical Sciences
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Major part of information will be available for population
When the data will become available and for how long
12 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
To conduct similar studies
From where data/document is obtainable
Fariborz Khorvash
What processes are involved for a request to access data/document
The data will send as soon as possible, after receiving the request
Comments