

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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**

Isfahan

**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**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 1792 2110

**Email**

fkhovash@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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 8138

**Email**

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

**Street address**

Hezarjarib Ave., Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3650 3584

**Fax**

+98 31 3668 5555

**Email**

fkhovash@med.mui.ac.ir

**Person responsible for scientific 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

**Street address**

Hezarjarib Ave., Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3650 3584

**Fax**

+98 31 3668 5555

**Email**

fkhorvash@med.mui.ac.ir

**Person responsible for updating data**

**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

**Street address**

Hezarjarib Ave., Isfahan University of Medical Sciences

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3650 3584

**Fax**

+98 31 3668 5555

**Email**

fkhorvash@med.mui.ac.ir

**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**