# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

23 Nov 2026

## Clinical trial on comparing efficacy of greater occipital nerve block with triamcinolone, lidocaine, triamcinolone with lidocaine and normal saline in treatment of migraine headache without aura

## Protocol summary


**Summary**

Objectives: The goal of this study is to compare efficacy of different protocols of greater occipital nerve block with placebo. Design: Single centered, randomized, double blind, placebo controlled clinical trial. Setting and conduct: Migrainous patients without aura aged between 18 and 65 years, with attack frequency of more than 4 times per month will be recruited. Patients will be entered to the study in three intervention and one control groups, The number of samples in each group will be 20. Patients will be treated with triamcinolone and normal saline in the first group, with lidocaine and normal saline in the second group, with lidocaine and triamcinolone in the third group and with normal saline in the fourth group. Frequency, duration and severity of headache and quality of life will be assessed before, after one and two weeks and after first and second months of intervention. Results will be compared with placebo. Inclusion criteria: patients with episodic migraine without aura; attack frequency more than 4 times per month; age between 18 and 65 years Exclusion criteria: no informed consent; prophylactic treatment started within last month; allergy to lidocaine; history of seizure; history of surgery in the occipital region; active infection in occipital region Intervention: Greater occipital nerve block in four groups of triamcinolone, lidocaine, triamcinolone with lidocaine and normal saline. Main outcome measures (variables): Headache frequency, duration and severity.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017070334879N1**
Registration date: **2017-08-10, 1396/05/19**
Registration timing: **prospective**
Last update:
Update count: **0**

**Registration date**

2017-08-10, 1396/05/19

**Registrant information**


**Name**

Siamak Abdi

**Name of organization / entity**

Neurology department- shariati hospital- Tehran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 6650 1321

**Email address**

s-abdi@sina.tums.ac.ir


**Recruitment status**

**Recruitment complete**

**Funding source**

Iranian center of neurological research, Tehran university of medical sciences

**Expected recruitment start date**

2017-08-23, 1396/06/01

**Expected recruitment end date**

2019-08-23, 1398/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Clinical trial on comparing efficacy of greater occipital nerve block with triamcinolone, lidocaine, triamcinolone with lidocaine and normal saline in treatment of migraine headache without aura

**Public title**
Efficacy of different protocols of greater occipital nerve block in treatment of migraine
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: patients with episodic migraine without aura with attack frequency of more than 4 times per month; age between 18 and 65 Exclusion criteria: failure to obtain informed consent; prophylactic treatment started within last month; allergy to lidocaine; history of seizure; history of surgery in the occipital region; active infection in occipital region
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**
Blocked randomization will be used. Size of each block will be 4.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Imam khomeini hospital complex Tehran university of medical sciences
**Street address**
Ethics committee of Imam khomeini hospital complex- Imam khomeini hospital complex - Keshavarz boulvard
**City**
Tehran
**Postal code**
**Approval date**
2017-06-08, 1396/03/18
**Ethics committee reference number**
IR.TUMS.IKHC.REC.1396.2549

## Health conditions studied

### 1

**Description of health condition studied**
Migraine
**ICD-10 code**
G43.0
**ICD-10 code description**
[Migraine without aura [common migraine

## Primary outcomes

### 1

**Description**
Attack frequency
**Timepoint**
just before and 1 and 2 months after intervention
**Method of measurement**
asked from patient and reported as attack per month

### 2

**Description**
Attack duration
**Timepoint**
just before and 1 and 2 months after intervention
**Method of measurement**
asked from patient and reported as attack duration

### 3

**Description**
Attack severity
**Timepoint**
just before and 1 and 2 months after intervention
**Method of measurement**
asked from patient and reported between 1 and 10

## Secondary outcomes

### 1

**Description**
quality of life
**Timepoint**
just before and 1 and 2 months after intervention
**Method of measurement**
MSQ questionnaire and VAS scale

### 2

**Description**
disability
**Timepoint**
just before and 1 and 2 months after intervention
**Method of measurement**
MIDAS questionnaire

## Intervention groups

### 1

**Description**
Intervention group 1: 20 mg of triamcinolone and normal saline (2.5 cc) is injected on each side of occipital tubercle with 3 or 5 cc syringe
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: 2 cc lidocaine of 2% and normal saline (2.5 cc) is injected on each side of occipital tubercle with 3 or 5 cc syringe
**Category**
Treatment - Drugs

### 3

**Description**
Intervention group 3: 20 mg of triamcinolone and 2cc of lidocaine 2% (2.5 cc) is injected on each side of occipital tubercle with 3 or 5 cc syringe
**Category**
Treatment - Drugs

### 4

**Description**
Control group: Normal saline (2.5 cc) is injected on each side of occipital tubercle with 3 or 5 cc syringe
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shariati hospital
**Full name of responsible person**
Siamak Abdi
**Street address**
EMG-NCV department, Shariati hospital, north kargar st
**City**
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Tehran University of Medical Sciences
**Full name of responsible person**
Dr Masoud Younesian
**Street address**
Iranian center of neurological research, Imam Khomeini hospital complex, Keshavarz boulvard
**City**
Tehran
**Grant name**
-
**Grant code / Reference number**
-
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Tehran University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Neurology department, shariati hospital, Tehran university of medial sciences
**Full name of responsible person**
Dr Mahsa Layegh
**Position**
Resident of neurology
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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Assistant professor of neurology

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## Person responsible for updating data

**Contact**

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Neurology department, Shariati hospital, Tehran university of medical sciences

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**Position**

Assistant professor of neurology

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*