

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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

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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 boulevard

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 boulevard

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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Dr Siamak Abdi

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Assistant professor of neurology

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Neurology department, Shariati hospital, Tehran university of medical sciences

Full name of responsible person

Siamak Abdi

Position

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Other areas of specialty/work

Street 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