Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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)
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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 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

Contact
Name of organization / entity
Neurology department, Shariati hospital, Tehran university of medical sciences
Full name of responsible person
Dr Siamak Abdi
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