Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Compression the efficacy of Topiramate and Propranolol in patients with migraine with Aura

Protocol summary

Study aim

Compression the efficacy of Topiramate and Propranolol in patients with migraine with Aura

Design

Patients are randomly divided into intervention groups and the study is design as a randomized and parallel group trial with double blinded outcome assessment. Randomisation was centralised based on simple randomization method using random digits table.

Settings and conduct

Thirty two patients with migraine with Aura in age group 18 to 65 years in Ahvaz Golestan hospital are studied into intervention groups (n=16). Participants, researchers responsible for data collection and analyses are blinded to the groups allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients who are candidates for coronary artery bypass surgery in age group 40 to 65 years; The exclusion criteria are patients with systolic blood pressure below 90 mmHg, heart rate below 65 beats per minute, incidence of tension-type headache attacks in the last month, previous history of analgesia or migraine specific medication, history of known allergy to Topiramate or Propranolol, kidney stones and depression.

Intervention groups

In the intervention group (1), Topiramate will be started at a daily dose of 25 mg and increased to 100 mg daily, depending on patient tolerance. The duration of taking the drug is three months and in the intervention group (2), Propranolol at a dose of 20 mg is prescribed twice a day for three months.

Main outcome variables

The degree of disability according to Migraine Disability Assessment (MIDAS) scale questionnaire before and after 3 months of taking the drug will be assessed and compared in the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201031049208N1**
Registration date: **2020-11-08, 1399/08/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-08, 1399/08/18**
Update count: **0**

Registration date

2020-11-08, 1399/08/18

Registrant information

Name

Saba Farashi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 2925

Email address

farashi.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compression the efficacy of Topiramate and Propranolol in patients with migraine with Aura

Public title

Compression the efficacy of Topiramate and Propranolol in patients with migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 18 to 65 years History of migraine with Aura (according to the definition of the international classification of headache disorders) Patients with the frequency of migraine attacks at least once a week

Exclusion criteria:

Systolic blood pressure below 90 mmHg Heart rate below 65 beats per minute Incidence of tension-type headache attacks in the last month Previous history of analgesia or migraine specific medication History of known allergy to Topiramate or Propranolol History of kidney stone History of depression

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group (1) and the odd numbers for the intervention group (2) are considered. According to the number of patients, they are randomly assigned to one of the intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are informed about the purpose and method of study. After receiving informed consent, they are blinded to the study groups to unify patients in terms of their empathy sense. Researchers responsible for data collection and analyses will also blinded to the groups allocation for preventing personal viewpoint.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

City

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Province

Khouzestan

Postal code

6135715794

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.AJUMS.REC.1398.932

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Assessing the degree of disability

Timepoint

Before and after 3 months of taking the drug

Method of measurement

Migraine Disability Assessment (MIDAS) scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (1): Topiramate will be started at a daily dose of 25 mg and increased to 100 mg daily, depending on patient tolerance. The duration of taking the drug is three months.

Category
Treatment - Drugs

2

Description
Intervention group (2): Propranolol at a dose of 20 mg is prescribed twice a day for three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable