

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of prophylactic effect of venlafaxine and topiramate in patients with chronic migraine : An open label randomized controlled trial

Protocol summary

Study aim

To determine and compare the prophylactic effect of venlafaxine and topiramate in patients with chronic migraine

Design

An open-label randomized controlled-trial aiming at comparing the prophylactic effects of venlafaxine vs topiramate on 100 patients with chronic migraine

Settings and conduct

One hundred patients with confirmed diagnosis of chronic migraine will be recruited in this study. Patients will be allocated in two groups (venlafaxine or topiramate) randomly using 4-blocked randomization method. Patients should stop using migraine prophylactic drugs and they will be asked to complete a prospective headache diary in 4 weeks. In titration period one group will receive 37.5 mg/day venlafaxine and another group will receive 25 mg/day topiramate and if it doesn't have any adverse effects, they should add one tablet to the primary dose each week and they will take 2 tablets per day (150 mg venlafaxine and 100 mg topiramate) until the end of 4 weeks. After titration period (4 weeks), patients will receive the maximum dosage that they can tolerate for 12 weeks. During 12 weeks patients will receive headache diary again and they can also take analgesic drugs if they have headache attack and record it in their headache diary.

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients who met the ICHD-3 criteria Age 20-55 years Exclusion criteria Taking migraine prophylactic drugs in the last 4 weeks Suffering from renal, cardiovascular and liver diseases Having major depression, bipolar disorder and psychosis Having hypertension and ocular hypertension Pregnancy or lactation

Intervention groups

50 migraine patient in venlafaxine group and 50 migraine patient in topiramate group

Main outcome variables

Mean frequency of migraine attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120227009157N8**

Registration date: **2018-07-10, 1397/04/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-10, 1397/04/19**

Update count: **0**

Registration date

2018-07-10, 1397/04/19

Registrant information

Name

Prof Mansoureh Togha

Name of organization / entity

Neurology department, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6670 2052

Email address

toghae@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of prophylactic effect of venlafaxine and topiramate in patients with chronic migraine : An open label randomized controlled trial

Public title
Comparison of prophylactic effect of venlafaxine and topiramate in patients with chronic migraine : An open label randomized controlled trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who met the ICHD-3 criteria Age 20-55 years
Exclusion criteria:
Taking migraine prophylactic drugs in the last 4 weeks
Suffering from renal, cardiovascular and liver diseases.
Having major depression, bipolar disorder and psychosis
Having hypertension or ocular hypertension
Pregnancy or lactation

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects will be randomized to one of the A(venlafaxine) or B(Topiramate) groups using 4 block randomization method. The main researcher and the patients are aware of the type of administered drugs. This is an open label randomized controlled trial.

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 Tehran University of Medical

Sciences
Street address
Sina hospital, Imam Khomeini Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
113746911

Approval date

2017-09-18, 1396/06/27

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.3516

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Number of migraine days

Timepoint

Before intervention and after 12 weeks intervention

Method of measurement

Headache diary

2

Description

Number of migraine attacks

Timepoint

Before intervention and after 12 weeks intervention

Method of measurement

Headache diary

3

Description

Maximum intensity of migraine attacks

Timepoint

Before intervention and after 12 weeks intervention

Method of measurement

Headache diary and Visual Analogue Scale

Secondary outcomes

1

Description

Headache Duration in hours

Timepoint

Before the intervention and after the intervention

period(12 weeks)
Method of measurement
Headache diary

2

Description
Responder rate
Timepoint
After the intervention period(12 weeks)
Method of measurement
Headache diary:30-50% decrease in primary endpoints relative to baseline

3

Description
Days of analgesic usage
Timepoint
Before the intervention and after the intervention period(12weeks)
Method of measurement
Headache diary

4

Description
Health care outcomes/quality of life Recommendations
Timepoint
Before the intervention and after the intervention period(12 weeks)
Method of measurement
HIT-6 score

Intervention groups

1

Description
Intervention group: Intervention group will receive 37.5 mg venlafaxine at the beginig of the intervention period and increase does up to 150 mg until 2 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group will receive 25 mg topiramate at the beginig of the intervention period and increase does up to 100 mg until 2 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Headache clinic, Sina hospital
Full name of responsible person

Prof. Mansoureh Togha
Street address
Sina hopital, Imam Khomeini Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
113746911
Phone
+98 21 6312 1506
Email
toghae@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mrs. Bahareh Pourghaz
Street address
Qods St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3610
Email
baharpourghaz@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr.Samaneh Haghghi
Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

Street address

Sina Hospital, Hasan Abad Sq., Imam Khomeini Ave.

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1506

Email

haghighi_sa@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Mansoureh Togha

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

Street address

Sina hospital, Hasan Abad Sq., Imam Khomeini Ave.

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1506

Email

toghae@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Mansoureh Togha

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

Street address

Sina hospital, Hasan Abad Sq., Imam Khomeini Ave.

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1506

Email

toghae@sina.tums.ac.ir

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

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

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

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

Data Dictionary

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