Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 (venaflaxine 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 venaflaxine 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 venaflaxine and 100 mg topiramate) untile the end of 4 weeks. After titration period (4 weeks), patients will recieve the maximum dosage that they can tolerate for 12 weeks. During 12 weeks patients will recieve 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 Suffeing 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)

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+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 Suffeing 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 adminestrated 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

۱۱۳۶۷۴۶۹۱۱

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

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+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.

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1417653761

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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 Haghighi

Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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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

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Prof. Mansoureh Togha

Position

Professor

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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

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