Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Comparative Study of Preventive Effects of Venlafaxine with Amitriptyline in Migrainous Patients

Protocol summary

Study aim

1- Determining and comparing the frequency of the number of attacks between the two groups receiving venlafaxine and amitriptyline before and 8 weeks after treatment 2- Determining and comparing the average length of attacks between the two groups receiving venlafaxine and amitriptyline before and 8 weeks after treatment. 3- Determining and comparing the severity of attacks between the two groups receiving venlafaxine and amitriptyline before and 8 weeks after treatment 4- Determining the demographic characteristics (age, sex, and duration of the disease) between the two groups receiving venlafaxine and amitriptyline

Design

Any patient who has been diagnosed with migraines and is eligible for admission will randomly receive one of the two drugs, amitriptyline 25 or venlafaxine 37.5, for 60 days in two 30-day intervals.

Settings and conduct

Migrainous patients will receive one of two drugs, amitriptyline or venlafaxine. While using the drugs, they will fill in the relevant questionnaire and the details of their attacks will be collected.

Participants/Inclusion and exclusion criteria

Entry Conditions: People with migraines, people who experience at least three attacks a month, people who have never used two drugs, amitriptyline, and venlafaxine, to manage their attacks. Persons Failure to enter: Pregnant women or women who are planning to become pregnant within the next two months. People with a history of seizures or specific cardiovascular or cerebral surgery. Patients with glaucoma, benign prostatic hyperplasia, or high blood pressure.

Intervention groups

Intervention group: Patients who will receive venlafaxine at a dose of 37.5 once a day for 8 weeks. Control group: Patients receiving amitriptyline at a dose of 25 daily for 8 weeks.

Main outcome variables

Number, severity, and duration of attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170814035697N6**
Registration date: **2020-12-25, 1399/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-25, 1399/10/05**
Update count: **0**

Registration date

2020-12-25, 1399/10/05

Registrant information

Name

Hamdolah Sharifi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2021-02-03, 1399/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Comparative Study of Preventive Effects of Venlafaxine with Amitriptyline in Migrainous Patients

Public title
Effects of venlafaxine and amitriptyline on migraines

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People with migraine People who experience 3 or more attacks each month People who have never used amitriptyline or venlafaxine to manage their attacks

Exclusion criteria:
People who are pregnant or planning to become pregnant in the next two months People with a history of specific cardiovascular or cerebral surgery People with a history of seizures People with high blood pressure people with Benign prostatic hyperplasia People with glaucoma

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Both drugs are in the same package. 40 packs of Venlafaxine 37.5 will be in a box called V and 40 packs of amitriptyline 25 will be in a box called A. 40 cards with the letter A and 40 cards with the letter V will be placed in a box. For each patient who is eligible to receive both drugs after the examination, one of the cards is accidentally taken out of the box and one of the two drugs venlafaxine or amitriptyline is given to the patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants in the project, researcher, and mentor will be blind to the drug used by patients. But the doctor will be informed about the medication. The medicines will be packed in similar envelopes and placed in two boxes with the signs that only the doctor will know about. Patients are first told that they will take one of the two drugs venlafaxine 37.5 or amitriptyline 25 randomly (e.g., first patient, amitriptyline, and second patient, venlafaxine, and so on), but depending on which drug they will consume, will be unaware.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences; Resalat Ave; Jahad Blvd; Urmia; West Azerbijan Provine; Iran

City
Urmia

Province
West Azarbaijan

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5714783734

Approval date
2020-06-02, 1399/03/13

Ethics committee reference number
IR.UMSU.REC.1399.089

Health conditions studied

1

Description of health condition studied
Migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
incidence of Headache

Timepoint
At the beginning of the study and two months after the start of the study

Method of measurement
The six-item Headache Impact Test. Headache Impact Test is a tool used to measure the impact headaches have on your ability to function on the job, at school, at home and in social situations.Your score shows you the effect that headaches have on normal daily life and your ability to function. Headache Impact Test was developed by an international team of headache experts from neurology and primary care medicine in collaboration with the psycho metricians who developed the SF-36®health assessment tool. This questionnaire was designed to help you describe and communicate the way

you feel and what you can not do because of headaches.

Secondary outcomes

1

Description
severity of attacks
Timepoint
At the beginning of the study and two months after the start of the study
Method of measurement
The six-item Headache Impact Test

2

Description
duration of attacks
Timepoint
At the beginning of the study and two months after the start of the study
Method of measurement
The six-item Headache Impact Test

3

Description
number of attacks
Timepoint
At the beginning of the study and two months after the start of the study
Method of measurement
The six-item Headache Impact Test

Intervention groups

1

Description
Intervention group: venlafaxine taking group. Intervention in this group: Patients will take one venlafaxine tablet with a dose of 37.5 per day made by Sami Saz Pharmaceutical Company for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: amitriptyline taking group. Intervention in this group: Patients will take one amitriptyline tablet with a dose of 25 per day made by Iran Daru Pharmaceutical Company for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic, Imam Khomeini Hospital
Full name of responsible person
Mohaddeseh Hedayat
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Imam Khomeini hospital; Ershad Ave; Modarres Blvd; Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
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Web page address
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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
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Mohaddeseh Hedayat

Position
University Student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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Associate professor

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Person responsible for updating data

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Hamdolah Sharifi

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Assistant professor

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
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