

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison Of The Effects Of Venlafaxine And Nortriptiline on Prevention of Migraine Headaches

Protocol summary

Summary

In this study two hundred patients with migraine headaches according to international headache society criteria are assigned randomly in two groups equally. All patients are selected between eighteen to forty five years old with at least one year history of migraine headache and at least three attacks in each month. One group take nortriptiline twenty five milligrams each night for three months and another group takes venlafaxine 37.5 milligrams two times daily at noon and night equal to seventy five milligrams daily for the same duration. Frequency of attacks in month, duration of attacks in hour and headache intensity is measured by Visual analogue scale (VAS) and six points behavioral rating scale (BRS-6) . All patients are evaluated in the beginning, after forty five and ninety days after taking the drugs. Patients with another kind of headaches, other neurologic problems, taking drugs other than migraine drugs, or any history of allergy or hypersensitivity to drugs which are used in study are not permitted. Patients and investigators and persons who analyse data in primary and middle stages of study are not aware of the intervention or drug types used by patients. All patients have written informed consent by supervision of ethical committee of Shahed University and can leave the study each time during it.

General information

Acronym

Venlafaxine in Migraine

IRCT registration information

IRCT registration number: **IRCT2017052930680N3**

Registration date: **2017-10-09, 1396/07/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-09, 1396/07/17

Registrant information

Name

Siamak Afshinmajd

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 9438

Email address

afshin@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-01-10, 1393/10/20

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Of The Effects Of Venlafaxine And Nortriptiline on Prevention of Migraine Headaches

Public title

The Effect of Venlafaxine on Prevention of Migraine Headaches

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Migraine headache according to international headache society Age between eighteen to

forty -five years old At least three attacks of headaches each month with more than four hours duration At least one year duration of headache attacks Exclusion Criteria: Any other type of headaches such as tension, cluster,... Other neurologic problems such as vertigo,vascular disorders, Parkinson,... Use of any other type of drugs,except drugs used in migraine headaches Any history of unwantedreaction or hypersensitivity to drugs in the study

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **201**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study patients who come to clinic randomly and every other one are assigned in the groups using Nortriptiline or Venlafaxine. The first group is selected by drawing lot.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Shahed University

Street address

Entrance of Tehran - Qom Highway

City

Tehran

Postal code

Approval date

2014-03-18, 1392/12/27

Ethics committee reference number

Shahed.REC.1392.47

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine(Idiopathic)common

2

Description of health condition studied

Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine (Idiopathic) classical

Primary outcomes

1

Description

Headache Intensity

Timepoint

At the beginning, after forty five and ninty days

Method of measurement

Visual Analogue Scale

2

Description

Headache Intensity

Timepoint

At the beginning, after forty five and ninty days

Method of measurement

6 Points Behavioral Rating Scale

3

Description

Frequency of headache attacks

Timepoint

At the beginning, after forty five and ninty days

Method of measurement

Number of headache attacks in one month

4

Description

Duration of headache attacks

Timepoint

At the beginning, after forty five and ninty days

Method of measurement

Average duration of headache attacks in hour according to patients expressions

Secondary outcomes

1

Description

Pruritus, Burning sensation and Redness of skin

Timepoint

Immediately after patient alarm

Method of measurement

Observation, examination and consultation with proper specialist

Intervention groups**1****Description**

Group one: All patients take nortriptyline twenty five(25) milligrams at night for three months

Category

Treatment - Drugs

2**Description**

Group Two: all patients take thirty - seven and half milligrams (37.5) at noon at the same amount at night for three months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Siamak Afshinmajd

Street address

keshavarz bld. Italia street

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahed University

Full name of responsible person

Zahra Kiasalari

Street address

Entrance of Tehran -Qom Highway

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, Shahed University

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**

Shahed University, Faculty of Medicine

Full name of responsible person

Siamak Afshinmajd

Position

Associate Professor of Neurology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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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