

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of effectiveness of venlafaxine with nortriptyline in migraine prophylaxis

Protocol summary

Summary

Objective: Comparison of the effectiveness of two types of drugs in migraine prophylaxis. Study design: Sampling, random, non-blind Study population: Patients that refer to neurology clinics of hospitals of the Islamic Azad University in Tehran in 2012-2014 years that suffer from migraine base on the diagnosis of the treating physician. Inclusion criteria: Patients with migrain that they did not receive eny other medicine in the past two months. Exclusion criteria: The incidence of major complications (side effects that need to cut the treatment, if they occuered) A sample of 120 patients with migraine that were referred to one of two study groups were formed two groups of sixty people. Interventions: drug venlafaxine 37.5 mg dose twice a day for the first group and drug nortriptyline dose of 25 mg once a day for the second group. Time of Intervention: prophylactic treatment with drugs listed in a period of one month. The outcomes: It is expected after a period of study in duration, intensity and frequency of migraine attacks will occur changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091524041N1**

Registration date: **2016-03-20, 1395/01/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-20, 1395/01/01

Registrant information

Name

Nima Mohsenzadeh Kermani

Name of organization / entity

Islamic Azad University Tehran Medical Branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 5621

Email address

nmohsenzadeh@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Islamic Azad University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of venlafaxine with nortriptyline in migraine prophylaxis

Public title

The effects of drugs on migraine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with migraine that they did not receive other drugs in the past two months. Exclusion criteria: The incidence of major complications (side effects that need to cut the treatment, if they happened)

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization:alternatly in order of presentation of paitients

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University Tehran
Medical Branch

Street address

Islamic Azad University Tehran Medical
Branch,Khaghani Avenue,Shariati Street,Tehran,IRAN

City

Tehran

Postal code

193951495

Approval date

2016-02-24, 1394/12/05

Ethics committee reference number

IR.IAU.TMU.REC.1394.30

Health conditions studied

1

Description of health condition studied

migrain

ICD-10 code

G43.0

ICD-10 code description

common migrain

Primary outcomes

1

Description

frequency of Migraine headache

Timepoint

Before the intervention,one month after intervention

Method of measurement

Questionnaire

2

Description

intensity of Migraine headache

Timepoint

Before the intervention,one month after intervention

Method of measurement

Questionnaire

3

Description

duration of Migraine headache

Timepoint

Before the intervention,one month after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the control group: oral medication nortriptyline(tablet)
25 mg once a day for a month(Made in Abidi Company)

Category

Treatment - Drugs

2

Description

In the intervention group: oral medication
venlafaxine(Tablet) 37.5 mg dose twice a day for one
month.(made in Abidi Company)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Hospital

Full name of responsible person

Mehdi Vahid Dastjerdi

Street address

Neurology Clinic, Bu-Ali Hospital,Imam Hossein
Square,Damavand Street,Tehran,IRAN

City

Tehran

2

Recruitment center

Name of recruitment center

Amir Almomenin Hospital

Full name of responsible person

Nima Mohsenzadeh Kermani

Street address

Sardar Jangal Street, Nazi Abad Street, Tehran, IRAN

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice Chancellor for research of Tehran Azad University of Medical Sciences

Full name of responsible person

Hassan Eftekhari

Street address

Vice Chancellor for Research, Islamic Azad University Tehran Medical Branch, Khaghani Avenue, Shariati Street, Tehran, IRAN

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 of Tehran Azad University of Medical Sciences

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**

Islamic Azad University Tehran Medical Branch

Full name of responsible person

Nima Mohsenzadeh Kermani

Position

Neurologist, Associate Professor

Other areas of specialty/work**Street address**

Islamic Azad University Tehran Medical Branch, Khaghani Avenue, Shariati Street, Tehran, IRAN

City

Tehran

Postal code**Phone**

+98 21 2258 5621

Fax**Email**

nmohsenzadeh@iautmu.ac.ir;
saloome.shahmirzadi@yahoo.com;
saloome.shahmirzadi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University Tehran Medical Branch

Full name of responsible person

Nima Mohsenzadeh Kermani

Position

Neurologist, Associate Professor

Other areas of specialty/work**Street address**

Islamic Azad University Tehran Medical Branch, Khaghani Avenue, Shariati Street, Tehran, IRAN

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Fax**Email**

nmohsenzadeh@iautmu.ac.ir;
saloome.shahmirzadi@yahoo.com;
saloome.shahmirzadi@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Islamic Azad University Tehran Medical Branch

Full name of responsible person

Nima Mohsenzadeh Kermani

Position

Neurologist, Associate Professor

Other areas of specialty/work**Street address**

Islamic Azad University Tehran Medical Branch, Khaghani Avenue, Shariati Street, Tehran, IRAN

City

Tehran

Postal code**Phone**

+98 212122585621

Fax**Email**

nmohsenzadeh@iautmu.ac.ir;
saloome.shahmirzadi@yahoo.com;
saloome.shahmirzadi@gmail.com

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