

# 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**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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## Person responsible for updating data

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## **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*