

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of the therapeutic effect of mirtazapine with venlafaxine in the treatment of tension headaches

#### Protocol summary

##### Study aim

Comparison of therapeutic effect of mirtazapine with venlafaxine in the treatment of tension headaches

##### Design

This study is an interventional and prospective study. Randomization and allocation of each eligible patient in both intervention and control groups will be done by random block method. The intervention is in the form of three blinds so that the patient and the researcher and analyzer will not know the type of drug to treat patients.

##### Settings and conduct

This is an interventional and prospective study that will be performed in 2021 in Al-Zahra and Kashani medical centers in Isfahan.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients for whom the diagnosis of tension headache has been confirmed by a neurologist. The patient has the consent to participate in the study. Exclusion criteria: Patients who do not agree to enter the study, suffer from chronic physical diseases such as kidney-liver, heart, lung, cancer, autoimmune, etc. and mental problems, a specialist doctor has diagnosed them with other headaches such as migraine

##### Intervention groups

Intervention group: Mirtazapine 15 mg daily Control group: Venlafaxine 5.37 g daily

##### Main outcome variables

Tension headaches

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210410050915N1**

Registration date: **2021-05-12, 1400/02/22**

Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**

Update count: **0**

##### Registration date

2021-05-12, 1400/02/22

##### Registrant information

###### Name

Maryam Alsadat Golabzadeh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3220 4715

###### Email address

msgolab2020@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of the therapeutic effect of mirtazapine with venlafaxine in the treatment of tension headaches

##### Public title

Therapeutic effect of mirtazapine with venlafaxine in the treatment of tension headaches

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

All patients for whom the diagnosis of tension headache has been confirmed by a neurologist. The patient has the consent to participate in the study.

**Exclusion criteria:**

Patients who do not have the consent to enter the study. Patients with chronic physical diseases such as kidney-liver, heart, lung, cancer, autoimmune, etc. and mental problems. A specialist doctor has diagnosed them with other headaches such as migraines.

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **130**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization and allocation of each eligible patient in both intervention and control groups will be done by random block method. The intervention is in the form of three blinds so that the patient and the researcher and analyzer will not know the type of drug to treat patients. The file numbers are entered in Excel, then the random number is selected from the data analysis command. This study has 2 groups that can be numbered from 1 to 2, respectively. We also want to have 65 people in each group. As a result, sequences 1 to 2 should be repeated 65 times each time. It is clear that the repetition of each number occurs once in each group, so select 1 for repeating each number and 65 for repeating the sequence. In this way, 130 units will be produced. Which patient is included in which group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The intervention is in the form of three blinds so that the patient and the researcher and analyzer will not know the type of drug to treat patients.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2021-02-19, 1399/12/01

**Ethics committee reference number**

IR.MUI.MED.REC.1399.1066

**Health conditions studied****1****Description of health condition studied**

Tension headaches

**ICD-10 code**

G44.0

**ICD-10 code description**

Cluster headaches and other trigeminal autonomic cephalgias (TAC)

**Primary outcomes****1****Description**

Reduce pain

**Timepoint**

Before the intervention, three months and six months later

**Method of measurement**

Comparison of therapeutic effect of mirtazapine with venlafaxine

**Secondary outcomes**

empty

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

Intervention group: Mirtazapine 15 mg daily

**Category**

Treatment - Drugs

**2****Description**

Control group: Venlafaxine 37.5 g daily

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Ahmad Chitsaz

**Street address**

Al-Zahra hospital, Sofeh St.,Isfahan,Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

alzahra@med.mui.ac.ir

### 2

#### Recruitment center

**Name of recruitment center**

Kashani Hospital

**Full name of responsible person**

Ahmad Chitsaz

**Street address**

Kashani ST

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

**Phone**

+98 31 3233 0091

**Email**

kashani@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Esfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, hezar jarib S.T

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Email**

research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan University of Medical Sciences

**Proportion provided by this source**

1

**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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ahmad Chitsaz

**Position**

Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal nerves

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St.,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 913 310 1971

**Email**

ahmadchitsaz@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ahmad Chitsaz

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal nerves

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St.,

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 913 310 1971

**Email**

ahmadchitsaz@med.mui.ac.ir

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 913 310 1971

**Email**

Gholabzadeh@yahoo.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Golabzadeh

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib St.,

**City**

Isfahan

**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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable