Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 2021in 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)
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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
Isfehan

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
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2

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Isfahan University of Medical Sciences, hezar jarib S.T
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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
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Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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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
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