Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

To survey the effects of Memantine in comparison routine treatment for improving tension-type headache

Protocol summary

Summary

The present study is designed with the aim of evaluating the efficacy and tolerability of Memantine for tension-type headache. This is a prospective randomized, open-label, clinical trial which will be conducted on patients with tension-type headache referred to Emam Reza outpatient clinic (Shiraz, Iran) based on eligibility criteria during 3-month period. The patients will be randomly assigned to receive Memantine (5-15mg) or Amitriptyline (20mg) for three months. Baseline characteristics of the participants include age, gender, BMI, and medication treatment schedules will be obtained by a date gathering form. As the primary outcome, migraine disability assessment scale will be measured before and after intervention. In addition, we will be considered the number of days with headache per month, and headache severity as secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081635710N2**
Registration date: **2017-09-17, 1396/06/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-17, 1396/06/26

Registrant information

Name
Ehsan Jelodari
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 71 3230 5884
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e_jelodari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2017-12-30, 1396/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To survey the effects of Memantine in comparison routine treatment for improving tension-type headache

Public title

Effects of Memantine on tension-type headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with confirmed tension-type headache; Aged between 18 and 65 years. Exclusion criteria: Patients with the history of smoking, or alcohol; Pregnancy or breastfeeding; Use of antipsychotics or antidepressants in the past 3 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done using a randomization table based on the registration number of the patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Headquarters Of Shiraz University of Medical Sciences, Zand St

City

Shiraz

Postal code

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.SUMS.REC.1396.59

Health conditions studied

1

Description of health condition studied

tension-type headache

ICD-10 code

G44.2

ICD-10 code description

Chronic tension-type headache

Primary outcomes

1

Description

Migraine disability assessment scale

Timepoint

Before intervention - 3 months after intervention

Method of measurement

MIDAS questionnaire

Secondary outcomes

1

Description

Headache severity

Timepoint

Before intervention - 3 months after intervention

Method of measurement

Visual analogue scale

2

Description

Number of headache days per month

Timepoint

Before intervention - 3 months after intervention

Method of measurement

patients' self-report

Intervention groups

1

Description

Intervention group: Memantine (5-15mg) every day for 3 months

Category

Treatment - Drugs

2

Description

Control group: Amitriptyline (20mg) every day for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic

Full name of responsible person

Ehsan Jelodari

Street address

Namazi square, Shahid Motahari Clinic

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University Of

Medical Science

Full name of responsible person

Dr. Seyed Baser Hashemi

Street address

Building of Shiraz University of Medical Sciences, Zand Ave

City

Shiraz

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, Shiraz University Of Medical Science

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

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Jelodari

Position

Resident of Neurology

Other areas of specialty/work

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ehsan2313@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Masoume nazeri

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Position

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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