Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of levtriastam versus amitriptyline on migraine attack in patients with migraine without aura: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of levtriastam versus amitriptyline on migraine attack without aura in patients with migraine. Design: a randomized clinical trial. Setting and conduct: The eligible patients with migraine who will refer to Sina Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 45 years; migraine without aura. Exclusion criteria: Pregnancy or breastfeeding; using prophylactic drugs for migraine; diabetes; liver failure; renal failure; hematologic disorders; cardiovascular diseases; depression; epilepsy; glaucoma. Intervention group 1: Tablet levtriastam 500 mg once a day for 6 months. Intervention group 2: Tablet amitriptyline 100 mg once a day for 6 months. Primary outcome: Number of migraine attacks in 1 and 2 and 6 months through history taking. Secondary outcome: Number of analgesic usage in 1 and 2 and 6 months through history taking. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703139014N152**
Registration date: **2017-03-22, 1396/01/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-22, 1396/01/02

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of levtriastam versus amitriptyline on migraine attack in patients with migraine without aura: a randomized clinical trial

Public title

Effect of levtriastam versus amitriptyline on migraine attack in patients with migraine without aura

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 45 years; migraine without aura. Exclusion criteria: Pregnancy or breastfeeding; using prophylactic drugs for migraine; diabetes; liver failure; renal failure; hematologic disorders;

cardiovascular diseases; depression; epilepsy; glaucoma.

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2017-03-04, 1395/12/14

Ethics committee reference number
IR.UMSHA.REC.1395.594

Health conditions studied

1

Description of health condition studied
Migraine without aura

ICD-10 code
G43.0

ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description
Number of migraine attacks

Timepoint
in 1 and 2 and 6 months

Method of measurement
through history taking

Secondary outcomes

1

Description
Number of analgesic usage

Timepoint
in 1 and 2 and 6 months

Method of measurement
through history taking

Intervention groups

1

Description
Intervention group 1: Tablet levtriastam 500 mg once a day for 6 months.

Category
Treatment - Drugs

2

Description
Intervention group 2: Tablet amitriptyline 100 mg once a day for 6 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Dr Mahsa Fathian

Street address
Sina Hospital, Mirzadeh Eshghi Ave.

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research the Technology,

Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan 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

Sina Hospital

Full name of responsible person

Dr Mahsa Fathian

Position

Resident of Neurology

Other areas of specialty/work

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Postal code

Phone

+98 81 3827 4184

Fax

Email

mahsa.fathian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Dr Mahsa Fathian

Position

Resident of Neurology

Other areas of specialty/work

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Postal code

Phone

+98 81 3827 4184

Fax

Email

mahsa.fathian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

Street address

School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax

Email

poorolajal@umsha.ac.ir

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