

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison effectiveness of Levetiracetam and Sodium Valproate in prevention of Migraine without aura

Protocol summary

Study aim

aims to compare the effects of two drugs,levetiracetam and sodium valpoate,on preventing migraine headache,and thus comparing the effects of these two drugs on improving quality of life,reducing the duration and number of migraine headache attacks

Design

The study population will be 100 patients referring to the clinic of Alavi Hospital in Ardabil City in 2017.These people are randomly divided into two distinct groups,and then studied.A group of 50 people will be prescribed levetiracetam.These subjects will be examined according to the pre-prepared questionnaire form the time of referral up to 3 months after administration of the drug in terms of intensity,duration and number of migraine headache attacks.The next group including 50 people will be prescribed sodium valproate and the criteria listed above will be examined.At the end,the obtained data will be compared between the two groups.

Settings and conduct

Patients referring to the clinic of Alavi hospital in Ardabil who were randomly assigned to two separate groups according to the pre- prepared questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria in this research include the age of 16 to 65 years old who will be candidate to achieve prophylaxis of migraine by being diagnosed with migraine headaches,and Exclusion criteria include pregnancy and lactation;liver and kidney failure;sedative medications;being smoker;and non-migraine headaches.

Intervention groups

effects of two drugs,levetiracetam and sodium valpoate,on preventing migraine headache.

Main outcome variables

improving quality of life,reducing the duration and number of migraine headache attacks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171011036717N1**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

Parham Sedighnia

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3371 5498

Email address

p.sedighnia@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Arabil University of Medical Sciences,Vice Cancellor for Research

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effectiveness of Levetiracetam and Sodium Valproate in prevention of Migraine without aura

Public title

The effectiveness of Levetiracetam and Sodium Valproate in Migraine headache prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: The age of 16 to 65 years old who will be candidate to achieve prophylaxis of migraine by being diagnosed with migraine headaches. pregnancy and lactation liver failure kidney failure sedative medication non-migraine headaches

Exclusion criteria:

Exclusion criteria: pregnancy and lactation; liver and kidney failure; sedative medication; being smoker; non-migraine headaches.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

Ardabil Complex University, Daneshgah st., Ardabil, Ardabil Province.

City

Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

IR.ARUMS.REC.1396.133

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Migraine Disability Assessment

Timepoint

Every month for three months

Method of measurement

Migraine Disability Assessment Test

Secondary outcomes

1

Description

Intensity of migraine attacks

Timepoint

Every month for three months

Method of measurement

Asking from patient

2

Description

The number of migraine attacks

Timepoint

Every month for three months

Method of measurement

Asking from patient

Intervention groups

1

Description

Sodium valproate, 500mg oral tablet, once a day for three months.

Category

Treatment - Drugs

2

Description

Levetiracetam, 250mg oral tablet, twice a day for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital in Ardabil

Full name of responsible person

Vahid Abbasi

Street address

Alavi Hospital.Moghadase Ardabili Street,Shahid Maadi Street

City

Ardabil

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5613974156

Phone

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Email

alavi@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Ardabil University of Medical Sciences

Full name of responsible person

Dr.Massoud Entezari Asl

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Ardabil Complex University, Daneshgah st., Ardabil, Ardabil Province

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m.entezari@arums.ac.ir

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, Ardabil University of Medical Sciences

Proportion provided by this source

100

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

Ardabil University of Medical Sciences

Full name of responsible person

Parham Sedigh Nia

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Abolfazl Atalu

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neuroscience

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Shahid maadi Street, Moghadase Ardabili Street, Alavi Hospital

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Person responsible for updating data

Contact

Name of organization / entity
Ardebil University of Medical Sciences
Full name of responsible person
Parham Sedigh Nia
Position
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A Level or less
Other areas of specialty/work
General Practitioner
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Province
Ardabil

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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