

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 valproate, 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 valproate, 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

Ardabil 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
Ethic Committee of Ardabil University of Medical Sciences
Street address
Ardabil Complex University, Daneshgah st., Ardabil, Ardabil Provice.
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

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5613974156

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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

Street address

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
Medical student
Latest degree
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