Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Haspital 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 intencity,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 campared 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)

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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:
Exlusion 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
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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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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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Dr. Abolfazl Atalu
Position
Assistant Professor
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Specialist
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Neuroscience
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Position

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Other areas of specialty/work

General Practitioner

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Web page address

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