

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The comparison of effect of levetiracetam and sodium valproate on seizure attacks frequency of 8-30 year old patients with juvenile myoclonic epilepsy

Protocol summary

Summary

(1) Objectives: The comparison of effect of levetiracetam and sodium valproate on seizure attacks frequency of 8-30 year old patients with juvenile myoclonic epilepsy. (2) Design: Single central, Phase 2 trial (3) Setting and conduct: A number of 62 patients (at the age of 8-30 years) with Juvenile myoclonic epilepsy were assigned in to equal groups. The first group was treated with Levetiracetam with the main dosage of 1000 mg daily and the second group was treated with sodium valproate, 800 mg daily. The efficacy of these two drugs was compared with each other by the changes occurred in frequency of seizures during 28 weeks. (4) Participants including major eligibility criteria: 62 patients. Inclusion criteria: Patients with juvenile myoclonic epilepsy; Age between 8 and 30; Absence of brain lesion in MRI; Normal neurologic physical examination. Exclusion criteria: Pregnancy; Secondary epilepsy; Levetiracetam, Lamotrigine or Sodium valproate receiving during last month; Severe organic disease; History of poor compliance(5) Intervention group: Tab Levetiracetam 250 mg orally twice a day for 28 weeks, from Sobhan Pharmaceutical Company. Control group: Tab Sodium valproate 200mg orally twice a day for 28 weeks, from Sobhan Pharmaceutical Company. (6): frequency of seizures

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112715567N1**

Registration date: **2014-02-15, 1392/11/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-15, 1392/11/26

Registrant information

Name

Fatemeh Sadr

Name of organization / entity

Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3012

Email address

sadr.fa@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2013-04-04, 1392/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of effect of levetiracetam and sodium valproate on seizure attacks frequency of 8-30 year old patients with juvenile myoclonic epilepsy

Public title

The comparison of effect of levetiracetam and sodium valproate on seizure attacks frequency of 8-30 year old

patients with juvenile myoclonic epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with juvenile myoclonic epilepsy; Age between 8 and 30; Absence of brain lesion in MRI; Normal neurologic physical examination.

Exclusion criteria: Pregnancy; Secondary epilepsy; Levetiracetam, Lamotrigine or Sodium valproate receiving during last month; Severe organic disease; History of poor compliance.

Age

From **8 years** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **62**

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand St, Golestan Blv.

City

Ahvaz

Postal code

Approval date

2013-12-01, 1392/09/10

Ethics committee reference number

ajums.REC.1392.200

Health conditions studied

1

Description of health condition studied

Generalized idiopathic epilepsy

ICD-10 code

G40.3

ICD-10 code description

Generalized idiopathic epilepsy and epileptic syndromes

Primary outcomes

1

Description

frequency of seizures

Timepoint

monthly

Method of measurement

according to history

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tab Levetiracetam 500 mg orally twice a day for 28 weeks, from Sobhan Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Control group: Tab Sodium valproate 400 mg orally twice a day for 28 weeks, from Sobhan Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Fatemeh Sadr

Street address

Esfand St, Golestan Blv.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mostafa Fegghi, MD

Street address

Esfand St, Golestan Blv.

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Ahvaz

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, Ahvaz Jundishapur 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**

Jundishapur University of Medical Sciences

Full name of responsible person

Fatemeh Sadr

Position

Assistant of Neurology

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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