

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of sodium valproate, levetiracetam, and lamotrigine on seizure attacks and EEG disorders in patients with juvenile myoclonic epilepsy: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of sodium valproate, levetiracetam, and lamotrigine on seizure attacks and EEG disorders in patients with juvenile myoclonic epilepsy. **Design:** a double blind randomized clinical trial. **Setting and conduct:** The eligible patients with juvenile myoclonic epilepsy who will refer to Imam Khomeini Clinic during the study period will be enrolled into the trial. **Inclusion criteria:** affected with juvenile myoclonic epilepsy; age of over 12 years. **Exclusion criteria:** having severe organic diseases, heart failure, liver disorder, renal disease, or electrolyte disorder; abnormal MRI image; mental retardation; pregnancy or breastfeeding; alcohol or drug dependence; needing to more than one drug for controlling seizure; noncompliance. **Intervention group 1:** oral levetiracetam 500 mg twice a day for 6 months. **Intervention group 2:** oral lamotrigine 100 mg twice a day for 6 months. **Control group:** Oral sodium valproate 500 mg once a day for 6 months. **Primary outcome:** Assessing seizure attacks before intervention, and 1, 2, and 6 months after intervention through history taking. **Secondary outcome:** Assessing EEG disorders before intervention, and 1, 2, and 6 months after intervention using electroencephalogram. **Randomization:** Random assignment of the patients to the intervention and control groups one at a time. **Blinding:** Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509079014N79**
Registration date: **2015-09-18, 1394/06/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-18, 1394/06/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of sodium valproate,

levetiracetam, and lamotrigine on seizure attacks and EEG disorders in patients with juvenile myoclonic epilepsy: a double blind randomized clinical trial

Public title

Comparison of the effect of sodium valproate, levetiracetam, and lamotrigine on seizure attacks and EEG disorders in patients with juvenile myoclonic epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: affected with juvenile myoclonic epilepsy; age of over 12 years. Exclusion criteria: having severe organic diseases, heart failure, liver disorder, renal disease, or electrolyte disorder; abnormal MRI image; mental retardation; pregnancy or breastfeeding; alcohol or drug dependence; needing to more than one drug for controlling seizure; noncompliance.

Age

From **12 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups one at a time.
Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double 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

2015-05-23, 1394/03/02

Ethics committee reference number

IR.UMSHA.REC.1394.71

Health conditions studied

1

Description of health condition studied

juvenile myoclonic epilepsy

ICD-10 code

G40.3

ICD-10 code description

Generalized idiopathic epilepsy and epileptic syndromes

Primary outcomes

1

Description

Assessing seizure attacks

Timepoint

before intervention, and 1, 2, and 6 months after intervention

Method of measurement

through history taking

Secondary outcomes

1

Description

Assessing EEG disorders

Timepoint

before intervention, and 1, 2, and 6 months after intervention

Method of measurement

using electroencephalogram

Intervention groups

1

Description

oral levetiracetam 500 mg twice a day for 6 months

Category

Treatment - Drugs

2

Description

oral lamotrigine 100 mg twice a day for 6 months.

Category

Treatment - Drugs

3

Description

oral sodium valproate 500 mg once a day for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Clinic

Full name of responsible person

Dr Sahar Moradi

Street address

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

City

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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

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Hamadan University of Medical Sciences, Shahid
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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 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

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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