Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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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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
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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