Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of levetiracetam and sodium valproate versus sodium valproate alone on epileptiform discharges in electroencephalogram in interictal phase in children with epilepsy: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of levetiracetam and sodium valproate versus sodium valproate alone on epileptiform discharges in electroencephalogram in the interictal phase in children with epilepsy

Design
This is a randomized clinical trial, phase II, in which 42 eligible children with epilepsy will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible children with epilepsy who will refer to Besat Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 2 to 15 years; Idiopathic or cryptogenic epilepsy Exclusion criteria: Severe seizure syndrome; Frequent convulsions

Intervention groups
Intervention group: Tablet levetiracetam 50 mg/kg daily for 60 year and tablet sodium valproate 20 to 30 mg/kg daily for one year Control group: Tablet sodium valproate 20 to 30 mg/kg daily for one year

Main outcome variables
Primary outcome: Assessing the epileptiform discharges in the interictal phase every 3 months for one year using electroencephalogram

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N246**
Registration date: **2018-10-22, 1397/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-22, 1397/07/30**
Update count: **0**

Registration date
2018-10-22, 1397/07/30

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 1838 0090

Email address
poorolajal@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-11-22, 1397/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of levetiracetam and sodium valproate versus sodium valproate alone on epileptiform discharges in electroencephalogram in interictal phase in children with epilepsy: a randomized clinical trial

Public title
Effect of levetiracetam and sodium valproate versus

sodium valproate alone on epileptiform discharges in electroencephalogram in interictal phase in children with epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 2 to 15 years; Idiopathic or cryptogenic epilepsy

Exclusion criteria:

Severe seizure syndrome; Frequent convulsions

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR.UMSHA.REC.1397.146

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

Assessing the epileptiform discharges in interictal phase

Timepoint

Every 3 months for one year

Method of measurement

Using electroencephalogram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet levetiracetam 50 mg/kg daily for 60 year and tablet sodium valproate 20 to 30 mg/kg daily for one year

Category

Treatment - Drugs

2

Description

Control group: Tablet sodium valproate 20 to 30 mg/kg daily for one year

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Mohammad Hussein Ebrahimi

Street address

Besat Hospital, Shahed Square

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone
+98 81 3364 0030
Email
dr.mhe46@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Dr Mohammad Hussein Ebrahimi
Position
Resident of Pediatrics
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
dr.mhe46@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Afshin Fayazi
Position
Pediatrician
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
Afshin_Fay@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Jalal Poorolajal
Position
Professor of Epidemiology
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Email

poorolajal@umsha.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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