Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 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

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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

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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

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Sponsors / Funding sources

1

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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
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
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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