

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Effect of levetiracetam monotherapy versus sodium valproate on treatment of children with generalized or focal epilepsy: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of levetiracetam monotherapy versus sodium valproate on the treatment of children with generalized or focal epilepsy

##### Design

This is a randomized clinical trial, phase II, in which 44 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible children with generalized or focal epilepsy referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 2 to 18 years, Generalized or focal epilepsy, Exclusion criteria: False seizures, Sustained brain injury, Acute psychosis, History of cerebral palsy, Pharmaceutic hepatitis, Liver disease, Kidney disease

##### Intervention groups

Intervention group: Levetiracetam syrup (manufactured by Lubel Daru Pharmaceutical Co.) 30 mg/kg every 12 hours for 18 months Control group: Sodium valproate syrup (manufactured by Razak Pharmaceutical Co.) 30-30 mg/kg every 12 hours for 18 months

##### Main outcome variables

Primary outcome: Number of seizures Secondary outcome: Blood complications

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N351**  
Registration date: **2020-04-04, 1399/01/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-04, 1399/01/16**

Update count: **0**

##### Registration date

2020-04-04, 1399/01/16

##### 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

2019-07-23, 1398/05/01

##### Expected recruitment end date

2020-12-21, 1399/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of levetiracetam monotherapy versus sodium valproate on treatment of children with generalized or focal epilepsy: a randomized clinical trial

**Public title**

Effect of levetiracetam monotherapy versus sodium valproate on treatment of children with generalized or focal epilepsy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 2 to 18 years, Generalized or focal epilepsy,

**Exclusion criteria:**

False seizures, Sustained brain injury, Acute psychosis, History of cerebral palsy, Pharmaceutic hepatitis, Liver disease, Kidney disease

**Age**

From **2 years** old to **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

**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**

2019-07-20, 1398/04/29

**Ethics committee reference number**

IR.UMSHA.REC.1398.338

**Health conditions studied****1****Description of health condition studied**

Focal epilepsy

**ICD-10 code**

G40.0

**ICD-10 code description**

Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset

**2****Description of health condition studied**

Generalized epilepsy

**ICD-10 code**

G40.3

**ICD-10 code description**

Generalized idiopathic epilepsy and epileptic syndromes

**Primary outcomes****1****Description**

Number of seizures

**Timepoint**

Every month

**Method of measurement**

By taking history

**Secondary outcomes****1****Description**

Blood complications

**Timepoint**

One month after the intervention

**Method of measurement**

By checking cell blood count

**Intervention groups****1****Description**

Intervention group: Levetiracetam syrup (manufactured by Lubel Daru Pharmaceutical Co.) 30 mg/kg every 12 hours for 18 months

**Category**

Treatment - Drugs

## 2

### Description

Control group: Sodium valproate syrup (manufactured by Razak Pharmaceutical Co.) 30-30 mg/kg every 12 hours for 18 months

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital in Hamadan city

##### Full name of responsible person

Dr Ghazal Sami

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3364 0030

##### Email

drsami.pediatrician@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

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##### Province

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##### 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 Ghazal Sami

#### Position

Resident of Pediatrics

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Pediatrics

#### Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Afshin Fayyazi

#### Position

Podiatrist

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Pediatrics

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afshin.fayyazi@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

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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