

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### levetiracetam versus carbamazepine monotherapy in the treatment of focal epilepsy of children

#### Protocol summary

##### Summary

The aim of this study is to compare the monotherapy effect of levetiracetam with carbamazepine in the treatment of children with focal epilepsy. For this purpose, children with age over one year and less than sixteen years old with newly diagnosed focal epilepsy, are entered to study. This is a randomized prospective study. Patients with Pseudo- seizures; Skin rash especially Stevens Johnson syndrome; Drug-induced hepatitis; Acute psychosis; Renal disorders; Severe agitation, are excluded from the study. The children are randomly treated by Levetiracetam or Carbamazepine. All patients are followed for the occurrence of seizures and side effects in one and six-month intervals. For investigation of side effects, liver function tests and complete blood count is done for all patients. For other considerable side effects such as drowsiness, restlessness and skin complications, patients are questioned.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015030821355N1**

Registration date: **2017-01-12, 1395/10/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-01-12, 1395/10/23

##### Registrant information

##### Name

Hosein Eslamiyeh

##### Name of organization / entity

Shahid Sadoughi University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 353724015

##### Email address

eslamieh@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2014-07-02, 1393/04/11

##### Expected recruitment end date

2015-03-05, 1393/12/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

levetiracetam versus carbamazepine monotherapy in the treatment of focal epilepsy of children

##### Public title

levetiracetam versus carbamazepine monotherapy in the treatment of focal epilepsy of children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Children with age over one year and less than sixteen years old with newly diagnosed focal epilepsy, No history of refractory seizures, No history of renal disease, No history of hepatic disease, No history of cerebral palsy, No history of antiepileptic drug consumption. Exclusion criteria: Pseudo- seizures, Skin rash especially Stevens Johnson syndrome, Drug-induced hepatitis, Acute psychosis, Renal disorders, Severe agitation, any other mild side effects that is unbearable

to the patient or parents

**Age**

From **1 year** old to **16 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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 Mashhad University of Medical Sciences

**Street address**

Mashhad University of Medical Sciences, Vakil abad

**City**

Mashhad

**Postal code**

9177948976

**Approval date**

2013-12-03, 1392/09/12

**Ethics committee reference number**

t-3181

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

Epilepsy

**ICD-10 code**

G40

**ICD-10 code description**

Episodic diseases

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

Occurrence of seizure

**Timepoint**

Six months from the beginning of study

**Method of measurement**

Description of patients and parents

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

Rise of liver enzymes

**Timepoint**

One month after beginning of the study

**Method of measurement**

Measurement of AST and ALT

**2****Description**

Skin rash

**Timepoint**

In the six month from the beginning of the study

**Method of measurement**

Observation

**3****Description**

Agitation

**Timepoint**

In the six month from the beginning of the study

**Method of measurement**

Parents report

**4****Description**

Somnolence

**Timepoint**

In the six month from the beginning of the study

**Method of measurement**

Parents report

**5****Description**

Advers blood effects

**Timepoint**

One month after beginning of study

**Method of measurement**

CBC examination

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

Control Group: carbamazepine group: This group will be treated with carbamazepine. In carbamazepine group, the

drug with the dose of 5 mg/kg/day is initiated and increases 5 mg/kg/week. finally, it reaches to the current dose of 15 mg/kg/per day. Then, with the same dose, the drug continues.

**Category**

Treatment - Drugs

**2****Description**

Intervention Group: levetiracetam group: This group will be treated with levetiracetam. In levetiracetam group, the drug with the dose of 10 mg/kg per day is initiated and increases 10 mg/kg/week. finally, it reaches to the current dose of 30 mg/kg/per day. Then, with the same dose, the drug continues.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Hosein Eslamiyeh

**Street address****City**

Mashhad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hosein Eslamiyeh

**Street address**

Ghaem hospital

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hosein Eslamiyeh

**Position**

Assistant professor, pediatric neurologist

**Other areas of specialty/work****Street address**

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Ghaem hospital

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**Web page address**

**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*