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
Ehics comittee 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
Occurence of seizure

Timepoint
Six months from the beginning of study

Method of measurement
Desciption of patients and parents

Secondary outcomes

1

Description
Rise of liver enzymes

Timepoint
One month after beginning of the study

Method of measurement
Measurment 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 montn 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. finlay, 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 of10 mg/kg per day is initiated and increases 10 mg/kg/week . finlay, it reaches to the current dose of30 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

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Person responsible for scientific inquiries

Contact

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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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