

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

A comparative study on the efficacy of Levetiracetam and Carbamazepine in the treatment of Rolandic seizures in children referred to the pediatric neurology clinics of Imam Hossein hospital- Isfahan University of Medical Sciences in 2019; An open-label randomized controlled trial

Protocol summary

Study aim

Evaluation and comparison of the efficacy of Levetiracetam and Carbamazepine in Rolandic epilepsy patients referred to pediatric neurology clinic of Imam Hossein Hospital of Isfahan University of Medical Sciences in 2019

Design

Randomized, not-blinded, controlled clinical trial with parallel groups

Settings and conduct

This study starts in the winter of 1397 by selecting 94 patients from the patients referred to the Neurology Clinic of Imam Hossein Hospital. They are randomly assigned to two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Children with BECTS (clinical diagnosis and EEG in favor of Rolandic epilepsy) with more than two attacks per year 2) Medicated with only one drug 3) Age above 4 years and under 12 years 4) Normal MRI Exclusion criteria: 1) Lack of consent to enter the study 2) Severe side effects and drug reactions to Levetiracetam or Carbamazepine 3) Multi-drug therapy 4) Inability to follow up the patients

Intervention groups

Patients, depending on their groups, treated with Levetiracetam syrup (100 mg/ml) at a dose of 30 mg/kg/day or Tegretol 20 mg/kg for 6 months

Main outcome variables

frequency, duration and severity of seizure attacks and drug side effects before treatment and every two months for 6 months

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190208042654N3**

Registration date: **2020-01-07, 1398/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-07, 1398/10/17**

Update count: **0**

Registration date

2020-01-07, 1398/10/17

Registrant information

Name

Vahid Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 3653

Email address

v.mansoury@edc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the efficacy of Levetiracetam

and Carbamazepine in the treatment of Rolandic seizures in children referred to the pediatric neurology clinics of Imam Hossein hospital- Isfahan University of Medical Sciences in 2019; An open-label randomized controlled trial

Public title
The Comparison of efficacy of Levetiracetam and Carbamazepine in the treatment of Rolandic seizures in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children with BECTS (clinical diagnosis and EEG in favor of Rolandic epilepsy) with more than two attacks per year Medicated with only one drug Age above 4 years under 12 years and Normal MRI
Exclusion criteria:
Lack of consent to enter the study Severe side effects and drug reactions to Levetiracetam or Carbamazepine Multi-drug therapy Inability to follow up the patients

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 94 patients will be selected consecutively, if they meet the criteria for entry, from the patients admitted to the neurology clinic of Imam Hossein children hospital. Then, they are assigned randomly to two groups by binary blocks. The randomization process is done by using a random numbered table to reach the desired sample number.

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 Isfahan University of Medical

Sciences
Street address
Hezar Jarib Ave
City
Isfahan
Province
Isfahan
Postal code
8174673461
Approval date
2019-10-09, 1398/07/17
Ethics committee reference number
IR.MUI.MED.REC.1398.349

Health conditions studied

1

Description of health condition studied

Rolandic seizure

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

Frequency, duration, and severity of seizure attacks and drug side effects

Timepoint

before treatment and every two months for 6 months

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Levetiracetam group treated with Lovebel syrup (100 mg/ml) with 30 mg/kg/day for 6 months

Category

Treatment - Drugs

2

Description

Control group: Carbamazepine group treated with Tegertol 20 mg/kg for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Parastou Ahadi

Street address

Emam Khomeini Ave

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Isfahan

Province

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Postal code

8195163381

Phone

+98 31 3386 8247

Email

Dr.ahadi65@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Jafar Nasiri

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Position

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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