Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Levebel 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

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Iran (Islamic Republic of)

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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
Isfehan
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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8195163381
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
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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
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Assistant Professor
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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