

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison between the efficacy and side effects of Levetiracetam versus Carbamazepine as mono therapy in treatment of partial epilepsy of the children between 2 to 14 years old

Protocol summary

Study aim

Comparison between the efficacy and safety of "Levetiracetam" versus "Carbamazepine" as monotherapy in treatment of partial epilepsy of the children between 2 to 14 years old who referred to the Imam Ali hospital

Design

The study is a clinical trial, randomized, with intervention and control groups. Based on previous studies, the sample size will be estimated according to the formula and the sample size ratio in each group will be 60 people.

Settings and conduct

It will take place in Imam Ali hospital as part of Alborz University of Medical Sciences in Iran. In this study, Levetiracetam and Carbamazepine will be randomly used for two groups. In the Carbamazepine group, the medicine will start with a dose of 5 mg/kg of body weight per day and increased by 5 mg/kg per week, and finally reaches the usual dose of 20 mg/kg per day. Then it will continue with the same dose. In the intervention group, the drug will start with a dose of 10 mg/kg per day and increased by 10 mg/kg per week to reach the usual dose of 40 mg/kg per day. Then it will continue with the same dose of medication. Patients will be examined at 4th, 12th, and 24th week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 2 to 14 years old, partial epilepsy as a new case, informed consent of patients' parents, no history of renal and liver diseases Exclusion criteria: History of seizure during the last 3 months, history of taking any anti-epileptic medicine, history of liver diseases, history of renal diseases, history of neurological disease under medical treatment

Intervention groups

Intervention Group: Group receiving Levetiracetam
Control Group: Group receiving Carbamazepine

Main outcome variables

Seizure frequency and medicine's side effects

General information

Reason for update

The increase in the number of samples compared to the proposal, the amendment regarding the dosage of the drugs used in the study, and the amendment concerning the absence of any sponsors other than the Alborz University of Medical Sciences in this study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170216032603N2**

Registration date: **2020-06-19, 1399/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-02, 1403/10/13**

Update count: **1**

Registration date

2020-06-19, 1399/03/30

Registrant information

Name

Hadi Montazer Lotf Elahi

Name of organization / entity

Tehran University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 6693 1493

Email address

h-mlotfelahi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-02, 1398/11/13
Expected recruitment end date
 2021-03-02, 1399/12/12
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison between the efficacy and side effects of Levetiracetam versus Carbamazepine as mono therapy in treatment of partial epilepsy of the children between 2 to 14 years old

Public title
 Analysis of the efficacy and side effects of Levetiracetam and Carbamazepine on treatment of children's epilepsy

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 2-14 years old Partial epilepsy as a new onset No history of renal disease No history of liver disease No history of cerebral palsy Acceptance to be part of this study
Exclusion criteria:
 Epilepsy in patients with any brain damage from three month ago History of taking any anti-epileptic medications History of liver disease History of renal disease History of neurological disease under medical treatment

Age
 From **2 years** old to **14 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
 Target sample size: **120**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Patients admitted or referred to the clinic will be divided into two groups based on the last digit of their file numbers. Patients with even last digit of file numbers will be in intervention group and patients will odd last digit of file numbers will be in control group. Intervention group will be treated by Levetiracetam and control group will be treated by Carbamazepine.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 The patients and the statistical analyzer were unaware of the drug used in each group.

Placebo
 Not used

Assignment

Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

After University of Art, West Bu Ali St., Nabovat Sq.

City

Karaj

Province

Alborz

Postal code

3149969415

Approval date

2020-02-02, 1398/11/13

Ethics committee reference number

IR.ABZUMS.REC.1398.208

Health conditions studied

1

Description of health condition studied

Partial Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

Medicine's Side Effects

Timepoint

Week 4, 12, 24 and if seizure or any side effects occur

Method of measurement

History and laboratory test result

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be treated with Levetiracetam drug. The drug is started at a dose of 10 mg/kg per day and is increased by 10 mg/kg

per week to reach the usual dose of 30 mg/kg per day.
The maximum dose in these patients was 40 mg/kg.
Then continue with the same dose.

Category

Treatment - Drugs

2**Description**

Control group: The control group treated with Carbamazepine started with a dose of 5 mg/kg per day and increased by 5 kg/kg per week to reach the usual dose of 15 mg/kg. The maximum dose in these patients was 20 mg/kg. Then continue with the same dose.

Category

Treatment - Drugs

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

Imam Ali Hospital

Full name of responsible person

Mrs Taftian

Street address

After University of Art, West Bu Ali St., Nabovat Sq.

City

Karaj

Province

Alborz

Postal code

3149969415

Phone

+98 26 3428 7483

Email

pezeshki@abzums.ac.ir

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

Alborz University of Medical Sciences

Full name of responsible person

Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, North Taleghani Blvd., Taleghani Square, Karaj Administrative Town, Alborz University of Medical Sciences

City

Karaj

Province

Alborz

Postal code

3149779453

Phone

+98 26 3419 7000

Email

info@abzums.ac.ir

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

Yes

Title of funding source

Alborz 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**

Alborz University of Medical Sciences

Full name of responsible person

Hadi Montazer Lotfelahi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

Street address

After University of Art, West Bu Ali St., Nabovat Sq.

City

Karaj

Province

Alborz

Postal code

3149969415

Phone

+98 26 3428 7339

Email

hmontazer.hadi@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Hadi Montazer Lotfelahi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

Street address

After University of Art, West Bu Ali St., Nabovat Sq.

City

Karaj

Province

Alborz

Postal code

3149969415

Phone

+98 26 3428 7339

Email

hmontazer.hadi@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Hadi Montazer Lotfelahi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Education

Street address

After University of Art, West Bu Ali St., Nabovat Sq.

City

Karaj

Province

Alborz

Postal code

3149969415

Phone

+98 26 3428 7380

Email

hmontazer.hadi@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected information can be shared

When the data will become available and for how long

After the publication of results

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Our data can be used with our permissions in academic classes

From where data/document is obtainable

Hadi Montazerlotfelahi with E-mail: h-mlotfelahi@razi.tums.ac.ir

What processes are involved for a request to access data/document

After a month we can share the data after complete understanding of aims

Comments