

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the Effect of Intermittent Oral Anticonvulsant Levetiracetam in Prevention of Recurrence of Fever and Convulsion in Children: a clinical trial study

Protocol summary

Study aim

The Effect of Intermittent Oral Anticonvulsant Levetiracetam in Prevention of Recurrence of Fever and Convulsion in Children

Design

This study is a non-blind clinical trial in a parallel design and with a control group. The study population will include all children aged 6 to 60 months with fever and seizures referred to Mohammad Kermanshahi Hospital of Kermanshah. 108 eligible children will be selected conveniently. Random table are used for randomization and participants are assigned to two groups of intervention and control.

Settings and conduct

This study, which will be performed in Mohammad Kermanshahi Hospital of Kermanshah, has not been blinded and all the parents of the participants and researchers are aware of the interventions received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 6 to 60 months; History of fever and seizures at least once Exclusion criteria: Patients with immunodeficiency; Neurological disorder and abnormal neurological examination; Seizures due to infection of the central nervous system and developmental disorder or progressive nervous disease;

Intervention groups

The intervention group will receive only one dose of levetiracetam 30-60 mg (orally), in case of recurrence of fever and seizures, will receive for 9 months. The control group was given acetaminophen only to reduce fever for 9 months.

Main outcome variables

Fever, Convulsions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N170**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Intermittent Oral Anticonvulsant Levetiracetam in Prevention of Recurrence of Fever and Convulsion in Children: a clinical trial study

Public title

The Effect of Intermittent Oral Anticonvulsant Levetiracetam in Prevention of Recurrence of Fever and Convulsion in Children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 6 to 60 months History of fever and seizures at least once

Exclusion criteria:

Patients with immunodeficiency Neurological disorder and abnormal neurological examination Seizures due to infection of the central nervous system and developmental disorder or progressive nervous disease

Age

From **6 months** old to **60 months** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table, patients are divided into two groups of 54. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-02-16, 1399/11/28

Ethics committee reference number

ir.kums.rec.1400.075

Health conditions studied

1

Description of health condition studied

Neonatal seizure

ICD-10 code

P90

ICD-10 code description

Convulsions of newborn

Primary outcomes

1

Description

Fever

Timepoint

At the beginning of the study, once a month for 9 months

Method of measurement

By asking the child's parents and the number of hospital visits

2

Description

Convulsions

Timepoint

At the beginning of the study, once a month for 9 months

Method of measurement

By asking the child's parents and the number of hospital visits

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive only one dose of levetiracetam 30-60 mg (orally), in case of recurrence of fever and seizures, will receive for 9 months.

Category

Treatment - Drugs

2

Description

The control group was given acetaminophen only to reduce fever for 9 months (Dosage based on weight 30 to 60 mg per kilogram of body weight).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Javad Shabani

Street address

Helal Ahmar Crossroads, Mohammad Kermanshahi Hospital

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Province

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Postal code

6713733135

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+98 83 3721 8204

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javadshabani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

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rkhodarahmi@mbrc.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Javad Shabani

Position

Resident Children

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Helal Ahmar Crossroads, Mohammad Kermanshahi Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mostafa Sedighi

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Helal Ahmar Crossroads, Mohammad Kermanshahi Hospital

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sedighi_mostafa@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Javad Shabani

Position

Resident Children

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available