Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City
Kermanshah
Province
Kermanshah
Postal code
6713733135
Phone
+98 83 3721 8204
Email
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
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3836 0014
Email
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
Street address
Helal Ahmar Crossroads, Mohammad Kermanshahi Hospital
City
Kermanshah
Province
Kermanshah
Postal code
6713733135
Phone
+98 83 3721 8204
Email
javadshabani@yahoo.com

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
City
Kermanshah
Province
Kermanshah
Postal code

6713733135

Phone

009837218204

Email

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

Pediatrics

Street address

Helal Ahmar Crossroads, Mohammad Kermanshahi Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6713733135

Phone

009837218204

Email

javadShabani@yahoo.com

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