

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of phenobarbital and levetiracetam in children with febrile seizures

Protocol summary

Study aim

Finding a low-risk and low-complication solution to reduce seizures following hyperthermia

Design

A clinical trial with two parallel groups, randomized, no blinding, on 100 sick children

Settings and conduct

This study is conducted on at least 100 children with febrile seizures (F.C.) in the age range of 6 to 60 months and who have indications for anticonvulsant treatment in Heshmatieh Sabzevar Hospital. In this study, children were randomly assigned to two groups under oral treatment with phenobarbital and the other group was treated with levetiracetam using a random number table. According to the entry criteria, people from both groups are initially tested to check blood cells, coagulation tests, and liver tests. Medical treatment begins and after the passage of at least 5 half-lives of the drug (about 15 days) from the start of the treatment, the serum concentration of the drug is measured by HPLC method. And the tests are repeated upon arrival and brain scans(EEG) are taken from patients to rule out epileptic syndromes.Finally, according to the design variables of presence or absence, the amount and intervals of seizures are examined as a result.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study
Convulsions followed by fever
No history of head injury
No history of infectious diseases in the central nervous system
Not suffering from diabetes and taking medications for certain diseases

Intervention groups

The intervention group of children suffering from febrile convulsions, which are divided into two groups. Phenobarbital drug is given to one group and levetiracetam to the other group And after 5 half-lives from the start of the drug, the serum level of the drug is measured.

Main outcome variables

Phenobarbital/ levetiracetam group. EEG. Age. Sex. Family history. History of seizures. Type of fever and convulsions. Intervals between seizures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221105056406N1**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

Mahsa Aliakbari sani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 4422 5355

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-16, 1401/08/25

Expected recruitment end date

2022-12-26, 1401/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of phenobarbital and levetiracetam in children with febrile seizures

Public title
Comparison of phenobarbital and levetiracetam in febrile seizures

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 6 months to 60 months Convulsions followed by fever
Exclusion criteria:
Unwillingness to participate in the study History of head trauma Diseases of the central nervous system Having diabetes Suffering from certain diseases Taking medicines for specific diseases

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization was used for randomization. sample allocation in the study was based on a random sequence provided by the statistics consultant (Table of random numbers). The sequence used was double blocks.

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 Sabzevar University of Medical Sciences
Street address
Tohidshahr Blvd

City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Approval date
2021-05-01, 1400/02/11
Ethics committee reference number
IR.MEDSAB.REC.1400.011

Health conditions studied

1

Description of health condition studied
Febrile convulsion (F.C)
ICD-10 code
R56.0
ICD-10 code description
Febrile convulsions

Primary outcomes

1

Description
Number of seizures after receiving levetiracetam
Timepoint
14 days after starting the drug
Method of measurement
Questionnaire and questions from the patient's mother

2

Description
The number of seizures after receiving phenobarbital
Timepoint
14 days after starting the drug
Method of measurement
Questionnaire and questions from the patient's mother

3

Description
Intervals between seizures after receiving levetiracetam
Timepoint
14 days after starting the drug
Method of measurement
Questionnaire and questions from the patient's mother

4

Description
Intervals between seizures after receiving phenobarbital
Timepoint
14 days after starting the drug
Method of measurement
Questionnaire and questions from the patient's mother

5

Description

Side effects after taking levetiracetam

Timepoint

14 days after starting the drug

Method of measurement

Questionnaire and questions from the patient's mother

6

Description

Side effects after taking phenobarbital

Timepoint

14 days after starting the drug

Method of measurement

Questionnaire and questions from the patient's mother

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: The intervention method is a group of children aged 6 months to 60 months who have seizures caused by fever and have indications for drug therapy. Phenobarbital drug is given to this group in the amount of 3 to 5 mg per kilogram daily in two divided doses, and after 5 half-lives from the start of the drug (about 15 days), the serum level of the drug is measured by hplc method. And the number of convulsions and the intervals between convulsions and the side effects of the drug are checked before and after taking the drug.

Category

Treatment - Drugs

2

Description

Intervention group: The intervention method is a group of children aged 6 months to 60 months who have seizures caused by fever and have indications for drug therapy. In this drug group, levetiracetam is given at a dosage of 10 to 20 mg per kg twice a day. and after 5 half-lives from the start of the drug (about 15 days), the serum level of the drug is measured by hplc method. And the number of convulsions and the intervals between convulsions and the side effects of the drug are checked before and after taking the drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatieh hospital

Full name of responsible person

Parastoo amiri

Street address

Asad abadi street

City

Sabzevar

Province

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Email

Amiri.parasto@gmail.com

Web page address

<http://www.medsab.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

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vc.Research@medsab.ac.ir

Web page address

<http://www.medsab.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Parastoo Amiri
Position
Statistical consultant
Latest degree
Specialist
Other areas of specialty/work
Public Health
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Associated professor
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Person responsible for updating data

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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

No - There is not 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