Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Levetiracetam versus Clobazam for prophylaxis of febrile seizures in children

Protocol summary

Study aim
Determining the effectiveness of levetiracetam and clobazam on preventing recurrence of febrile convulsion
Design
Clinical trial, two-arm, parallel-group, unblinded, randomized in a sequential manner Phase 3 on 80 patients, 40 patients in each group
Settings and conduct
Patients are divided into two groups. In each group, one of the drugs levetiracetam or clobazam is prescribed to prevent Febrile convulsion in febrile illnesses in the next year. Recurrence of febrile seizures in the next year in each group is assessed.
Participants/Inclusion and exclusion criteria
Children with febrile convulsion without neurologic diseases and metabolic disorders
Intervention groups
The clobazam group and the levetiracetam group, each group taking the drug for a specific days after fever starts and the recurrence of febrile convulsion in the next year are evaluated.
Main outcome variables
Incidence of febrile convulsion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210911052441N1**
Registration date: **2025-06-23, 1404/04/02**
Registration timing: **retrospective**

Last update: **2025-06-23, 1404/04/02**
Update count: **0**
Registration date
2025-06-23, 1404/04/02

Registrant information
Name
Fatemeh Zamanyan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5541 3316
Email address
zamanyan-f@kaums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-19, 1399/12/01
Expected recruitment end date
2021-08-22, 1400/05/31
Actual recruitment start date
2021-03-25, 1400/01/05
Actual recruitment end date
2021-11-09, 1400/08/18
Trial completion date
2022-11-11, 1401/08/20

Scientific title
Levetiracetam versus Clobazam for prophylaxis of febrile seizures in children

Public title
Levetiracetam versus Clobazam for prophylaxis of febrile seizures
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children with febrile seizures
Exclusion criteria:
Neurologic disease Metabolic disorder epilepsy trauma meningitis
Age

From **6 months** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was performed using a random number table based on the sample size obtained by the software. Odd numbers were assigned to the clobazam group and even numbers to levetiracetam, and accordingly, the patients were divided into two groups of 40 each, receiving clobazam and levetiracetam. Treatment was prescribed to the patients by a pediatric neurologist.

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 kashan University of Medical Sciences

Street address

Shahid Beheshti Hospital, Ghotb-e Ravandi Blvd., Kashan, Iran

City

Kashan

Province

Isfehan

Postal code

8715981151

Approval date

2021-01-26, 1399/11/07

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.213

Health conditions studied

1

Description of health condition studied

Febrile convulsion

ICD-10 code

R56.0

ICD-10 code description

Febrile convulsions

Primary outcomes

1

Description

Number of febrile seizure recurrences in treated children

Timepoint

One year later

Method of measurement

Oral questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Levetiracetam: Levetiracetam syrup 30mg/Kg per dose, used for 48 hours after the onset of fever. This syrup is drawn up with a syringe according to the dose and given to the child.

Category

Prevention

2

Description

Intervention group: Clobazam, Clobazam tablets at a dose of 1mg/Kg, were used for 48 hours after the onset of fever. The tablets were dissolved in water according to the dose and fed to the child.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Fatemeh Zamanian

Street address

Shahid Beheshti Hospital, Ghotb-e Ravandi Blvd., Kashan, Iran

City

Kashan

Province

Isfehan

Postal code

8715981151

Phone

+98 31 5558 9333

Email
zamanyan-f@kaums.ac.ir

Web page address
http://beheshti.kaums.ac.ir/default.aspx

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Dr. Gholamali Hamidi

Street address
5th of Qotb –e Ravandi Blvd. P.O.Box: 8715988141, Kashan, IRAN

City
Kashan

Province
Isfehan

Postal code
8715988141

Phone
+98 31 5554 2999

Fax
+98 31 5557 5057

Email
research@kaums.ac.ir

Web page address
https://research.kaums.ac.ir/%DA%86%D8%A7%D8%B1%D8%AA?cid=18

Grant name
Dr. Gholamali Hamidi, Vice Chancellor for Research and Technology, Kashan University of Medical Sciences

Grant code / Reference number
99215

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

Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Fatemeh Zamanian

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

Street address
5th of Qotb –e Ravandi Blvd. P.O.Box: 87159.1151, Kashan, IRAN

City
Kashan

Province
Isfehan

Postal code
87159.1151

Phone
+98-31-55540026-31

Email
zamanyan-f@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Fatemeh Zamanyan

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
Shahid Beheshti hospital, Hekmat 56 St.,Ghotb-e Ravandi Blvd.,Kashan, Iran

City
Kashan

Province
Isfehan

Postal code
87159.1151

Phone
+98 31 5541 3316

Fax

Email
dr.fa_zamanyan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Fatemeh Zamanyan

Position
Resident

Latest degree
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Postal code

8715981151

Phone

+98 31 5541 3316

Fax

Email

dr.fa_zamanyan@yahoo.com

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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study outcome data can be shared after being filtered

When the data will become available and for how long

6 months after publishing of results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Registered research with an ethical approval code

From where data/document is obtainable

Research Office, Medical school, KAUMS

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

The data request is processed by the researcher after approval of the research deputy of the medical school

Comments