

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of diazepam and clobazam in preventing the recurrence of febrile seizures in children aged 6 months to 5 years of age admitted to Kashan Shahid Beheshti Hospital

Protocol summary

Summary

(1) Objectives: To compare the effect of diazepam and clobazam in preventing the recurrence of febrile seizures in children. (2) Design: Clinical trial. (3) Setting and conduct: Double blinded. (4) Participants: The main inclusion criteria is the age range from 6 months to 5 years and the first episode of febrile seizure (rectal temperature grater than 38 degrees centigrade). Patients with CSF infections, acute electrolyte disturbances, previous history of seizures without fever or an underlying neurological condition were excluded from the study. Also in case of parents' dissatisfaction or their lack of cooperation patients would be omitted from the study. (5) Intervention: Preventive treatment were given with 0.33 mg/kg of diazepam orally three times a day and 1 mg/kg of clobazam orally two times a day for 48 hours at the time of fever. (6) Main outcome measures: The relapse within one year after the first occurrence.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070318344N1**

Registration date: **2014-09-23, 1393/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-23, 1393/07/01

Registrant information

Name

Shirin Vafae

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

shirinvafae@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2013-02-03, 1391/11/15

Expected recruitment end date

2014-02-04, 1392/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of diazepam and clobazam in preventing the recurrence of febrile seizures in children aged 6 months to 5 years of age admitted to Kashan Shahid Beheshti Hospital

Public title

Comparison of clobazam and diazepam in preventing the recurrence of febrile seizures

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: children aged 6 months to 5 years with the first attack of febrile convulsion(rectal temperature greater than 38° C)/ Exclusion criteria: Patients who have

CNS infection and/or acute electrolyte imbalance and a history of previous seizure in the absence of fever; lack of cooperation or loss to follow up(for example changing the place of living); parents' discontent to participate in the study; having an underlying neurological disorder.

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kashan University of Medical Sciences ethics committee

Street address

Vice chancellor for research, Kashan Medical Sciences complex, Ghotbe Ravandi Blvd.

City

Kashan

Postal code**Approval date**

2013-01-23, 1391/11/04

Ethics committee reference number

29/5/1/4867/پ

Health conditions studied**1****Description of health condition studied**

Febrile seizure

ICD-10 code

R56.0

ICD-10 code description

Febrile convulsions

Primary outcomes**1****Description**

Recurrence of febrile seizures

Timepoint

Every three months during the intervention in a period twelve months

Method of measurement

asking the parents and visit by the pediatric neurologist

Secondary outcomes**1****Description**

Drugs side effects

Timepoint

Every three months during the intervention in a period twelve months

Method of measurement

asking the parents and visit by the pediatric neurologist

Intervention groups**1****Description**

Oral diazepam at a dose of 0.33 mg per kilogram of body weight per dose three times a day for 48 hours after the onset of fever

Category

Treatment - Drugs

2**Description**

Oral clobazam at a dose of 1 mg per kilogram of body weight per dose twice a day for 48 hours after the onset of fever

Category

Treatment - Drugs

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

Kashan Shahid Beheshti Hospital

Full name of responsible person

Dr.Shirin Vafaei

Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd.

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Vice Chancellor for research, Pezeshk Blvd., Ghotbe Ravandi Blvd.

City

Kashan

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

Yes

Title of funding source

Vice Chancellor for research, Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Shirin Vafaei

Position

Pediatrics resident

Other areas of specialty/work**Street address**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty