Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparative study of diazepam and clobazam in prevention recurrence of febrile seizure in children with age range of 6 month to 6 years of old admitted to Gorgan Taleghani hospital in 2011-2012

Protocol summary

Summary

In this investigation, tow drugs, diazepam and clobazam, will be studied for evaluating prevention of febrile seizure recurrence in patients admitted in Gorgan Taleghani Hospital. Study is randomized, not referred and single central. Inclusion criteria includes patients with simple febrile seizure that their parents worry about recurrence of febrile seizure or live away medical centers and have no access to medical facilities and also children that have multiple caregiver. Exclusion criteria includes: 1) patients that have no generalized seizure or have focal signs and seizure takes more than 15 minutes and occurs more than one time in 24 hours, neurological abnormalities and abnormal neurologic examination and developmental disorders; 2) progressive neurological disease; 3) seizures during infection of the central nervous; 4) diagnosis is not febrile seizure and there are other causes and 5) abnormal EEG. 140 patients will be studied in each group. Diazepam takes as 0.33 mg/kg/dose Q 8h and clobazam takes bases on weight body in 2.5, 5, 7.5 and 10 mg/kg dosage. The research will be started in 2011 and results involving episodes of fever every 3 months, drug side effects and seizure recurrence will be registered in a check list.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071514001N1**
Registration date: **2013-08-09, 1392/05/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-09, 1392/05/18

Registrant information

Name

Mahdi Jlili Akbarian

Name of organization / entity

Golestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

The cost of the plan funds of the Research and Technology Deputy of Golestan University of Medical Sciences

Expected recruitment start date

2011-11-06, 1390/08/15

Expected recruitment end date

2012-11-05, 1391/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of diazepam and clobazam in prevention recurrence of febrile seizure in children with age range of 6 month to 6 years of old admitted to Gorgan Taleghani hospital in 2011-2012

Public title

comparison diazepam and clobazam in prevention recurrence of febrile seizure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria includes patients with simple febrile seizure that their parents worry about recurrence of febrile seizure or live away medical centers and have no access to medical facilities and also children that have multiple caregiver. Exclusion criteria includes: 1) patients that have no generalized seizure or have focal signs and seizure takes more than 15 minutes and occurs more than one time in 24 hours, neurological abnormalities and abnormal neurologic examination and developmental disorders; 2) progressive neurological disease; 3) seizures during infection of the central nervous; 4) diagnosis is not febrile seizure and there are other causes and 5) abnormal EEG.

Age

From **6 years** old to **72 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Research and Thecnology Deputy, Golestan University of Medical Sciences

Street address

Falsafi Higher Education Bilding, beginning of Shastkola roade,

City

Gorgan

Postal code

Approval date

2011-11-06, 1390/08/15

Ethics committee reference number

191390081504

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 seizure

Timepoint

Every 3 months iduring intervention

Method of measurement

mg/kg

Secondary outcomes

1

Description

Drug side effects

Timepoint

Every 3 monthes during intervention

Method of measurement

By asking parents

Intervention groups

1

Description

Treatment by diazepam Chemical composition: 7-chloro-1,3-dihydro-1-methyl-5-phenyl-1-benzodiazepin-, C16H13ClN2O , molecular weight: 284.7 Dosage: 0.33 mg/kg Frequency of drug use: 3 times per day Duration of drug use: 48 hours

Category

Treatment - Drugs

2

Description

Treatment by clobazam Chemical composition: Chloro-1-methyl-5-phenyl-1,5-benzodiazepine, C16H13ClN2O2 , molecular weight: 300.74 Dosage: 2.5 mg for Children weighing less than 5 kg 5 mg for Children weighing 6-10 kg 7.5 mg for Children weighing 11- 15 kg 10 mg for Children weighing more than 15 kg Frequency of drug use: 2 times per day, every 12 hours Duration of drug use: 48 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Seoideh Amouian
Street address
Janbazan Boulevard, Taleghani Hospital
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research and Thecnology Deputy, Golestan University of Medical Sciences
Full name of responsible person
Mohammad Jafar Golalipour
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research and Thecnology Deputy, Golestan 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
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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