

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The Comparative Study of Diazepam with Two Different Doses in Prevention of Febrile Seizure Recurrence and its Complications in Children Aged 6 Months to 6 Years Old

Protocol summary

Summary

The purpose of this study is to compare the efficacy and side effects of the low-dose diazepam and recommended dose of diazepam for prevention of recurrence of febrile seizures in children 6 months to 6 years old. Inclusion criteria for the study Will considered the children 6 months to 6 years (male and female) with generalized tonic-clonic seizure that takes less than 15 minutes and can occur only once in 24 hours . And exclusion criteria will be included who do not have mentioned conditions And do not have neurological disorders and also neurologic progressive underlying disease or seizure cause by meningitis or electrolyte imbalance, or who had abnormal EEG. The study population will selected of patients referred to Taleghani hospital with first simple febrile seizure and selected parallel in the two groups. The sample size were included 140 patients in each group. .there is no blindness in this study so patients and physicians will be aware of the type of treatment. Finally, our intervention will be compare the effect of different doses of the diazepam in the prevention of febrile seizures . Samples will be collected in years 2012 and 2013 and will be followed for each sample to 1 year. Finally, by comparing different doses of diazepam in preventing febrile seizure can be prevented occurrence of adverse consequences of the disease by determining the best therapeutic dose And this way help to better control the patient disease

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102719700N1**

Registration date: **2015-02-14, 1393/11/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-14, 1393/11/25

Registrant information

Name

shima shekari

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 173243031020

Email address

shekari61@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Govermetal

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative Study of Diazepam with Two Different Doses in Prevention of Febrile Seizure Recurrence and its Complications in Children Aged 6 Months to 6 Years Old

Public title

The Comparative Study of Diazepam with Two Different

Doses in Prevention of Febrile Seizure Recurrence and its Complications in Children Aged 6 Months to 6 Years Old

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patient who do not have generalized seizure and a focal sign and Seizure prolong more than 15 minute and seizure more than 1 time in a day; Abnormal neurological function abnormal neurological examination and development disorder; Progressive neurological disease; Seizure due to central nerves system infection. Exclusion criteria: Seizure for other reasons is not FC (epilepsy (epilepsy, electrolyte disorders, trauma, etc.); The presence of abnormal EEG.

Age

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

Gender

Both

Phase

N/A

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

1

Registry name

The Comparative Study of Diazepam with Two Different Doses in Prevention of Febrile Seizure Recurrence and its Complications in Children Aged 6 Months to 6 Years Old Referred to Taleghani Hospital of Gorgan in 2012-2013

Secondary trial Id

1723059307208

Registration date

2014-10-19, 1393/07/27

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Golestan University of Medical Sciences

Street address

Central Organization of Golestan University of Medical Sciences, Boulevard Hyrkan, Gorgan, Golestan.

City

Gorgan

Postal code

4918936316

Approval date

2014-10-19, 1393/07/27

Ethics committee reference number

017230593072080

Health conditions studied

1

Description of health condition studied

Febrile Seizure

ICD-10 code

R50.R69

ICD-10 code description

Febrile convulsions

Primary outcomes

1

Description

Febrile Seizure

Timepoint

one year

Method of measurement

questionnaire

Secondary outcomes

1

Description

Side effects

Timepoint

one year

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Diazepam, dose: 0.3 mg for each kg of body weight, frequency of use: 3, duration: 8 hours

Category

Prevention

2

Description

Intervention group: Diazepam, dose: 0.3 mg for each kg of body weight, frequency of use: 2, duration: 12 hours

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Taleghani

Full name of responsible person

Shima Shekari

Street address

Central Organization of Golestan University of Medical Sciences, Boulevard Hyrkan, Gorgan, Golestan.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Golestan University of Medical Sciences

Full name of responsible person

Siamak Rajaei

Street address

Central Organization of Golestan University of Medical Sciences, Boulevard Hyrkan, Gorgan, Golestan.

City

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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

Vice Chancellor for Research 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

Name of organization / entity

Golestan University of Medical Sciences

Full name of responsible person

Shima Shekari

Position

Resident of Pediatric / students

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Person responsible for scientific inquiries

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Position

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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