

# 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**

Gorgan

## 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**

Gorgan

**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

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Speide Amouian

**Position**

Professor of Neurology

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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Resident of Pediatric / students

**Other areas of specialty/work**

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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*