

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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, two 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 1554 7525

##### Email address

ethic-committee@goums.ac.ir

#### 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-, C16H13CIN2O , 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, C16H13CIN2O2 , 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**

Gorgan

## 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 Gosalipour

**Street address**

Falsafi Higher Education Bilding, beginning of  
Shastkola roade,

**City**

Gorgan

**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

**Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Mahdi Jalili Akbarian

**Position**

MD

**Other areas of specialty/work**

**Street address**

Taleghani Hospital, Janbazan Boulevard

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**Phone**

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drmja2007@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Sepodeh Amouian

**Position**

Assistant professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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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*