

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative study of the effect of diazepam suppositories and oral diazepam in the prophylaxis of febrile seizures in children referred to Amir Kabir Hospital of Neurology in 2016

#### Protocol summary

##### Summary

Aim of this study Comparative study of the effect of Diazepam suppositories and oral Diazepam in the prophylaxis of febrile seizures in children referred to neurology clinic in Amir Kabir Hospital in 2016. This study is clinical trials and double blind. We will divide children 6 months to 60 months with febrile seizures referred to neurology clinic in Amir Kabir Hospital in two groups. We treat patients by 0.3 milligram in kilogram Oral Diazepam TDS in start of febrile to control febrile in first group. We treat patients by 0.5 milligram in kilogram Suppository Diazepam TDS in start of febrile to control febrile in second group. We will record number of frequent of febrile seizures in duration of treatment after one years. Inclusion criteria: 6 months to 60 months with febrile seizures Exclusion criteria: seizures with metabolic causes; seizures with central nervous system causes

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070320258N50**  
Registration date: **2017-07-06, 1396/04/15**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-06, 1396/04/15

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor and Research, Arak University of Medical Sciences

##### Expected recruitment start date

2016-02-19, 1394/11/30

##### Expected recruitment end date

2018-02-19, 1396/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of the effect of diazepam suppositories and oral diazepam in the prophylaxis of febrile seizures in children referred to Amir Kabir Hospital of Neurology in 2016

##### Public title

Comparative study of the effect of diazepam suppositories and oral diazepam in the prophylaxis of febrile seizures in children referred to Amir Kabir Hospital of Neurology in 2016

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 6 months to 60 months with febrile seizures Exclusion criteria: seizures with metabolic

causes; seizures with central nervous system causes

### 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: **212**

### 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

Ethics committee Arak University Of Medical Sciences

##### Street address

Dr Mohammad Rafiei, Vice chancellor for research,  
Payambar azam complex, Basij square, Sardasht, Arak

##### City

Arak

##### Postal code

38149578558

##### Approval date

2016-02-15, 1394/11/26

##### Ethics committee reference number

IR.ARAKMU.REC.1394.303

## Health conditions studied

### 1

#### Description of health condition studied

febrile seizures

#### ICD-10 code

R56.0

#### ICD-10 code description

Febrile convulsions

## Primary outcomes

### 1

#### Description

febrile seizures

#### Timepoint

before treatment and end of one years

#### Method of measurement

Number times of incidence

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: We treat patients by 0.3 milligram in kilogram Oral Diazepam TDS in start of febrile to control febrile in first group.

#### Category

Prevention

### 2

#### Description

Intervention group: We treat patients by 0.5 milligram in kilogram Suppository Diazepam TDS in start of febrile to control febrile in second group.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amirkabir hospital

##### Full name of responsible person

Dr Shariatmadari

##### Street address

Amirkabir hospital, Parastar square, Arak

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Arak University of  
Medical Sciences

##### Full name of responsible person

Dr Mohammad Rafiee

##### Street address

Vice chancellor for research, Payambar Azam  
Complex, Basij square, Sardasht, Arak

##### City

Arak

**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, Arak 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**

Amirkabir hospital

**Full name of responsible person**

Dr Shariatmadari

**Position**

Faculty member, Pediatric pediatrician

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

Amirkabir hospital, Parastar square

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 863222003

**Email**

alish9270@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Shariatmadari

**Position**

Faculty member

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

Amirkabir hospital, Parastar square

**City**

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**Postal code**

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**Web page address**

-

**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ali Shariati

**Position**

medicine student

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

Payambar Azam Complex, Basij Square, Sardasht, Arak

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**Postal code**

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**Phone**

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**Fax**

+98 863222003

**Email**

alish9270@gmail.com

**Web page address**

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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*