

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of efficacy of zinc sulfate on seizure recurrence during one year after first simple febrile seizure

#### Protocol summary

##### Summary

Febrile seizure (FS) is the most common type of childhood seizures which occurs in 2-5% of children. Based on some other studies, zinc level in children with febrile seizure is lower than in children without seizure. The purpose of this study is to evaluate efficacy of zinc sulfate on FS recurrence during the year after first simple FS. A randomized, clinical trial, will be conducted on 100 children aged 18-60 months with first simple FS and normal zinc level ( more than 70µg/dL ) whom will be admitted to Shahid Sadoughi Hospital , Yazd, Iran. The children will be distributed into two groups. In group one , 50 children will receive 2mg/kg/day zinc sulfate orally for six months and in the second group as control group , they will receive a placebo . Then , they will be followed up every three months for one year for the recurrence of febrile seizure , timing of recurrence and side effects .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201211262639N9**

Registration date: **2012-12-06, 1391/09/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-12-06, 1391/09/16

##### Registrant information

##### Name

Razieh Fallah

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,  
Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3822 4000

##### Email address

fallah@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Shahid Sadoughi University of  
Medical Sciences , Yazd, Iran .

##### Expected recruitment start date

2012-03-28, 1391/01/09

##### Expected recruitment end date

2014-03-20, 1392/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of efficacy of zinc sulfate on seizure  
recurrence during one year after first simple febrile  
seizure

##### Public title

Effect of zinc sulfate on recurrence of febrile seizure

##### Purpose

Other

##### Inclusion/Exclusion criteria

Inclusion criteria : 1. Aged 18-60 months 2. With first  
simple febrile seizure 3. Weight and height more than 3  
percentile 4. Normal hemoglobin level and MCV 5. Not  
receiving a zinc combinations within the past one month  
6. Normal zinc level Exclusion criteria: 1. presence of any  
serious systemic diseases(cardiac, renal, metabolic ,  
malignancy or rheumatologic ) 2. History of previous  
afebrile seizure 3. with neurodevelopmental delay or  
mental retardation 4. with acute CNS infection :

meningitis , encephalitis

### Age

From **1 year** old to **5 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

##### Street address

Bahonar Square, Central Building of University

##### City

Yazd

##### Postal code

##### Approval date

2012-11-21, 1391/09/01

##### Ethics committee reference number

119121

## Health conditions studied

### 1

#### Description of health condition studied

Febrile convulsions

#### ICD-10 code

R56.0

#### ICD-10 code description

Febrile convulsions

## Primary outcomes

### 1

#### Description

recurrence of febrile seizure

### Timepoint

every three months for one year

### Method of measurement

Taking history and physical examination

### 2

#### Description

timing of recurrence of febrile seizure

#### Timepoint

every three months for one year

#### Method of measurement

Taking history and physical examination

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

every three months for one year

#### Method of measurement

Taking history and physical examination

## Intervention groups

### 1

#### Description

2mg/kg/day zinc sulfate orally for six months

#### Category

Treatment - Drugs

### 2

#### Description

a placebo in control group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi Hospital

##### Full name of responsible person

Razieh Fallah MD

##### Street address

Ave sina St, Shahid Ghandi Blvd,

##### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran .

**Full name of responsible person**

Dr.Fatemah Ezoddini

**Street address**

Bahonar Square, Central Building of University

**City**

Yazd

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran .

**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****Person responsible for scientific inquiries****Contact**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

**Full name of responsible person**

Razieh Fallah

**Position**

Pediatric Neurologist , Associate professor

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

Shahid Sadoughi Hospital, Ave sina St, Shahid Ghandi Blvd

**City**

Yazd

**Postal code****Phone**

+98 35 1822 4000

**Fax****Email**

FALLAH@ssu.ac.ir

**Web page address****Person responsible for updating data****Contact****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*