

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

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Email address

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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**

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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