Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effectiveness of two different doses of ferrous sulfate on recurrence rate, one year after the first febrile convulsion(FC) in children one to five years old without iron deficiency anemia

Protocol summary

Study aim

Comparison of the effectiveness of two different doses of ferrous sulfate on the frequency distribution of recurrence within one year after the first febrile convulsion

Design

Clinical trial with parallel,double-blind,randomized,phase 2 in 100 patients.A random number table was used for randomization.

Settings and conduct

Children one to five years old, who have been hospitalized in the pediatric ward of Shahid Sadoughi Hospital in Yazd since June 1400 due to the first febrile convulsion; After obtaining the parents' consent, they enter the study. They are then randomly divided into two groups to prescribe two different doses of ferrous sulfate syrup and followed up every three months for one year. A pediatric resident who evaluates the outcome and the participants are kept blind to the study groups.

Participants/Inclusion and exclusion criteria

Login:The age of the child should be in the range of 12 to 60 months,The first febrile convulsion,Hemoglobin levels and mean red blood cell volume are in the normal range.No entry:Developmental delay,History of seizures without previous fever,Serious systemic disease,History of intolerable side effects of oral iron.

Intervention groups

Pediatrics one to five years old with the first seizure of febrile convulsion,One group iron sulfate one milligram per kilogram of body weight and the other group of iron sulfate three milligram per kilogram of body weight for one year is prescribed.Iron sulfate syrup per The two groups are similar and from the same manufacturer.

Main outcome variables

Recurrence of febrile convulsion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048243N1**
Registration date: **2021-05-27, 1400/03/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-27, 1400/03/06**
Update count: **0**

Registration date

2021-05-27, 1400/03/06

Registrant information

Name

Saeed Zakerzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3628 4379

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-26, 1400/03/05

Expected recruitment end date

2021-09-27, 1400/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of two different doses of ferrous sulfate on recurrence rate, one year after the first febrile convulsion(FC) in children one to five years old without iron deficiency anemia

Public title
Evaluation of the effectiveness of ferrous sulfate in preventing recurrence of febrile convulsion

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The Age of the Child should be in the Range of 12 to 60 Months With first febrile convulsion Normal hemoglobin level and mean corpuscular volume(MCV)

Exclusion criteria:
The Patient has Mental Retardation or Developmental Delay The Patient has a history of previous afebrile seizure Existence of Serious Systemic Disease in the Patient(Heart,Liver,Renal Dysfunction ,Rheumatology Disease,Peptic Ulcer,IBD) with acute CNS infection : meningitis , encephalitis

Age
From **12 months** old to **60 months** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization, individual, table of random numbers,

Blinding (investigator's opinion)
Double blinded

Blinding description
The children studied are randomly selected and the therapeutic dose is selected using a random number table. To blind the study, after randomly selecting the samples, the dose of the drug in each group is calculated and prescribed by a pediatrician.The assessor is a pediatric resident and is unaware of the type of group selected and the dose of medication. Participants also become blind to study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address
Central Administration, Bahonar Sq

City
Yazd

Province
Yazd

Postal code
8916978477

Approval date
2019-11-11, 1398/08/20

Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.194

Health conditions studied

1

Description of health condition studied
febrile convulsion

ICD-10 code
R56.0

ICD-10 code description
Febrile convulsions

Primary outcomes

1

Description
Repeated febrile seizures

Timepoint
One year

Method of measurement
observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: receiving ferrous sulfate drops of 1 mg / kg

Category
Prevention

2

Description
Intervention group 2: receiving ferrous sulfate drops of 3 mg / kg

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Shahid sadoughi hospital
Full name of responsible person
Zakerzadeh Forushani saeed
Street address
Shahid Ghandi Blvd, Safaieh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mirzayi Masoud
Street address
Central Administration, Bahonar Sq,Yazd University
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dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Saeed Zakerzadeh
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only data on age, sex, medication dose, and main outcome (recurrence of febrile seizures) will be shared.
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
Researchers working in medical universities
Under which criteria data/document could be used
Data requested by other researchers for comparison with similar studies.
From where data/document is obtainable
Zahra Nafei email adress: z.nafeie@ssu.ac.ir
What processes are involved for a request to access data/document
If you need to receive the data, send a message via email so that after the review, it will be provided to the applicant within a maximum period of one month.
Comments