Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of efficacy of topiramate and topiramate with supplement ferrous sulfate on monthly frequency, severity, and disability score of migraine headaches in 5-15 year old migraineur children without iron deficiency

Protocol summary

Summary

This study will be done to answer this question that whether supplement ferrous sulfate treatment can reduce monthly frequency, severity, and disability score of migraine headaches in migraineur children without iron deficiency. In a clinical trial, sixty 5-15 year old children with migraine headache and without iron deficiency (serum hemoglobin, iron and ferritin levels in normal limits) who would be referred to pediatric neurology clinic of Shahid Sadoughi University of Medical Sciences, Yazd, Iran and prophylactic therapy would be indicated in them, will be distributed randomly into two groups. In group I, 2 mg/kg/day of topiramate and in group II, 2mg/kg/day of topiramate and 2mg/kg/day of ferrous sulfate will be given .The drugs will be continued for three months and the children will be followed up monthly for three consecutive months. Primary outcomes include monthly frequency, severity, and duration and disability score of migraine headache that will be compared before and after three months of treatment. Severity of headache will be assessed by asking each child to grade majority of headache pain on 10-point scale as no pain = scale of 0 and the most severe pain = 10. Headaches disability will be assessed by Pediatric Migraine Disability Assessment score questionnaire. Secondary outcome include more than 50 % of reduction in monthly headache frequency and clinical side effects. The trial uses computer generated equal simple randomization by random numbers and data collectors, outcome assessors and data analysts are kept blinded to the allocation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504042639N15**
Registration date: **2015-05-06, 1394/02/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-06, 1394/02/16

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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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of efficacy of topiramate and topiramate with supplement ferrous sulfate on monthly frequency, severity, and disability score of migraine headaches in 5-15 year old migraineur children without iron deficiency

Public title
Ferrous sulfate in migraine headaches of children
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Children aged 5-15 years , Having migraine headache based on International Headache Society Criteria , Having one or more headache attack per week , Having moderate or severe headache disability , Having no iron deficiency (serum hemoglobin, iron and ferritin levels in normal limits) , Have not received iron combinations within the past two months , Not used any migraine preventive therapy Exclusion criteria: Secondary headaches such as epilepsy or other neurologic disorders, Irregular drugs usage, Discontinuation of iron usage for more than one week
Age
From **5 years** old to **15 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
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 of Shahid Sadoughi University of Medical Sciences , Yazd, Iran
Street address
Central building of university , Bahonar Square
City
Yazd
Postal code
Approval date
2014-04-19, 1393/01/30
Ethics committee reference number
17/1/223397/پ

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Monthly frequency of headache
Timepoint
before and three months after treatment
Method of measurement
asking from patient

2

Description
severity of headache
Timepoint
before and three months after treatment
Method of measurement
asking from patient

3

Description
duration of headache
Timepoint
before and three months after treatment
Method of measurement
asking from patient

4

Description
Pediatric Migraine Disability score
Timepoint
before and three months after treatment
Method of measurement
asking from patient

Secondary outcomes

1

Description
side effects
Timepoint
monthly until three months after treatment
Method of measurement

clinical exam and asking from patients

Intervention groups

1

Description
Tablet of 25 and 50 mg of topiramate of Daroupakhsh Co, Iran in dosage of 2 mg/kg/day single dose for three months
Category
Treatment - Drugs

2

Description
Tablet of 25 and 50 mg of topiramate of Daroupakhsh Co, Iran in dosage of 2 mg/kg/day single dose and tablet of 50 mg ferrous sulfate of Daroupakhsh Co, Iran in dosage of 2 mg/kg/day single dose for three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric neurology clinic of Shahid Sadoughi University of Medical Sciences, Yazd, Iran
Full name of responsible person
Dr.Razieh Fallah
Street address
Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd, I.R.Iran
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
central building of university , Bahonar Square
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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
Name of organization / entity
Shahid Sadoughi University of Medical Sciences , Yazd , Iran
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Pediatric Neurologist , Associate professor
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Person responsible for updating data

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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