

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

+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

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

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

Name of organization / entity

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

Full name of responsible person

Dr.Razieh Fallah

Position

Pediatric Neurologist , Associate professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd, I.R.Iran

City

Yazd

Postal code

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

dr.raziehfallah@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

Full name of responsible person

Dr.Razieh Fallah

Position

Pediatric Neurologist , Associate professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd, I.R.Iran

City

Yazd

Postal code

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

dr.raziehfallah@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences , Yazd
, Iran

Full name of responsible person

Dr.Razieh Fallah

Position

Pediatric Neurologist , Associate professor

Other areas of specialty/work

Street address

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid
Ghandi Blvd, Yazd, I.R.Iran

City

Yazd

Postal code

Phone

+98 35 3822 4000

Fax

+98 35 3822 4100

Email

dr.raziehfallah@yahoo.com

Web page address

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