

# 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

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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

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Shahid Sadoughi University of Medical Sciences , Yazd  
, Iran

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Dr.Razieh Fallah

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### 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*