

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of efficacy of topiramate alone and topiramate with supplement vitamin D3 on monthly frequency, severity, and disability score of headaches in 5-15 year old migraineur children without vitamin D3 deficiency

Protocol summary

Summary

This study will be done to answer this question that whether or not topiramate with supplement vitamin D3 is more efficient than topiramate alone in reduction of monthly frequency, severity, and disability score of headaches of without vitamin D3 deficiency migraineur children. In a clinical trial, sixty 5-15 year old children with migraine headache, with normal hemoglobin level and mean corpuscular volume (hemoglobin level more than 11.5g/dl and mean corpuscular volume more than 80 fL) and sufficient vitamin D3 level (more than 30 ng/mL) 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 one 500000 unit vitamin D3 pearl weekly will be given. The drugs will be continued for two months and the children will be followed up monthly for two consecutive months. Primary outcomes include monthly frequency, severity, duration and disability score of migraine headache that will be compared before and after two 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: **IRCT201701092639N20**

Registration date: **2017-01-10, 1395/10/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-10, 1395/10/21

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

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of efficacy of topiramate alone and topiramate with supplement vitamin D3 on monthly frequency, severity, and disability score of headaches in 5-15 year old migraineur children without vitamin D3 deficiency

Public title
Efficacy of topiramate alone and topiramate with supplement vitamin D3 on migraine headaches in 5-15 year old migraineur children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: children aged 5-15 years old; having migraine headache based on International Headache Society Criteria; having one or more headache attack per week; having moderate or severe headache disability; having normal hemoglobin level and mean corpuscular volume (hemoglobin level more than 11.5g/dl and mean corpuscular volume more than 80 fL); having sufficient vitamin D3 level (more than 30 ng/mL); have not received vitamin D3 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 drugs usage for more than one week; allergy to topiramate or vitamin D3; vitamin D3 level more than 80 ng/mL.

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)
Single 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 Yazd Medical Sciences University, Yazd, Iran
Street address
Central building of university, Bahonar square
City
Yazd
Postal code
Approval date
2015-11-24, 1394/09/03
Ethics committee reference number
IR.SSU.MEDICINE.REC.1394.376

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 two months after treatment
Method of measurement
Asking from patient

2

Description
Severity of headache
Timepoint
Before and two months after treatment
Method of measurement
Asking from patient

3

Description
Duration of headache
Timepoint
Before and two months after treatment
Method of measurement
Asking from patient

4

Description
Pediatric Migraine Disability score
Timepoint
Before and two months after treatment
Method of measurement

Secondary outcomes

1

Description

Frequency of more than 50 % of reduction in monthly headache frequency

Timepoint

Before and two months after treatment

Method of measurement

Asking from patient

2

Description

Clinical side effects

Timepoint

Before and two 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 two months

Category

Treatment - Drugs

2

Description

One weekly 500000 unit vitamin D3 pearl from Daroupakhsh Co, Iran and tablet of 25 and 50 mg of topiramate of Daroupakhsh Co, Iran in dosage of 2 mg/kg/day single dose for two 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, Ebnsina Blvd, Shahid Ghandi Blvd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Dr. Amirhoshang Mehrparvar

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

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

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Web page address

Person responsible for scientific

inquiries

Contact

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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