Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 topiramat 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

Questionnaire

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
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Person responsible for scientific

inquiries

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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