Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of efficacy of topiramate alone and topiramate with omega-3 fatty acid in prophylaxis of headaches in 5-15 year old children with migraine

Protocol summary

Study aim
Topiramate and topiramate with omega-3 in pediatric migraine

Design
A randomized parallel group clinical trial

Settings and conduct
This study will be done to answer this question that whether or not topiramate with omega-3 capsule 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, 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 capsule of omega-3 daily 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

Participants/Inclusion and exclusion criteria
5-15 year old children with migraine

Intervention groups
In group.I topiramate 2mg/kg/day , group.II topiramate 2mg/kg/day and omega-3 daily

Main outcome variables
Monthly frequency of headache

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20091027002639N23**
Registration date: **2020-03-31, 1399/01/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-31, 1399/01/12**
Update count: **0**

Registration date
2020-03-31, 1399/01/12

Registrant information

Name
Razieh Fallah
Name of organization / entity
Shahid Sadoughi University of Medical Sciences, Yazd, Iran
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-07, 1397/12/16

Expected recruitment end date

2020-04-19, 1399/01/31

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 omega-3 fatty acid in prophylaxis of headaches in 5-15 year old children with migraine

Public title

Efficacy of topiramate and topiramate with omega-3 fatty acid in prophylaxis of children migraine headaches

Purpose

Prevention

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 have not received omega-3 combinations within the past two months did not use any migraine preventive therapy

Exclusion criteria:

secondary headaches such as epilepsy or other neurologic disorders allergy to topiramat or omega-3 discontinuation of drugs usage for more than one week irregullar drugs usage

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

Participants are randomly assigned following simple randomization procedures (computerized random numbers) to 1 of 2 treatment groups and allocation ratio was 1:1 for the two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

of Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Street address

Central building of university, Bahonar square

City

Yazd

Province

Yazd

Postal code

8915836846

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.027

Health conditions studied

1

Description of health condition studied

migraine headache

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
Clinical side effects
Timepoint
Before and two months after treatment
Method of measurement
Clinical exam and asking from patients

Intervention groups

1

Description
Control group: 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
Intervention group: One daily capsule of omega-3 from 21st Century Co, USA and 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Razieh Fallah
Position
Professor,Pediatric Neurologist
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available