Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial to comparison the effect of omega-3 supplements and placebo on pediatric migraine prophylaxis in children treated with valproate sodium

Protocol summary

Summary

Migraine is the most frequent type of headache in children and preventive therapy is an important part of its management. It has been shown that administration of omega-3 fatty acids maybe reduces migraine headache attack frequency but because of different and not enough information especially in children, we decide to do this study. The purpose of this study is to show efficacy and safety of omega-3 fatty acid supplements in prophylaxis of migraine headache in children. In this randomized double blind clinical trial study, at least twenty four 5-14 year old children with migraine headache whom were referred to Pediatric Neurology Clinic of Besat Hospital and Imam Khomeini Clinic in Hamedan are distributed into two groups. In one group (case) tablet or syrup of valproate sodium with one omega-3 capsule contain of 1 gr fish oil will be prescribed and in other one (control) tablet or syrup of valproate sodium with one placebo capsule (without any active ingredient) will be given. Number, severity and disability grade of migraine headache and clinical general impression are to be compared before and after three months of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092914809N1**
Registration date: **2013-11-30, 1392/09/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-30, 1392/09/09

Registrant information

Name
Mahsha Sangestani
Name of organization / entity
Hamedan University of Medical Science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Science

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to comparison the effect of omega-3 supplements and placebo on pediatric migraine prophylaxis in children treated with valproate sodium

Public title

Effects of omega-3 supplements on prophylaxis of pediatric migraine

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1.children in 5-14 years old age

2.Having migraine headache based on International Headache Society Criteria 3.Having frequent or disabling headaches that prophylactic therapy indicated in them (one or more headache attack per week or, three or more headache attacks per month or, more than one school day lost per month) Exclusion Criteria: 1.Diagnosis changes each time during the study 2.Secondary headaches or other neurologic disorders 3.Not to use drugs correctly

Age

From **5 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Placebo capsules with the same color, package, and shape as omega-3 capsules are produced by Zahravi Pharmaceutical Company. Patients are considered in one of two groups, A or B, with simple random sampling method and the code will be assigned to each of them. The patient and physician are unaware of the contents of the medical groups. The patients will be treated by the physician and they will be followed for at least 3 months. The frequency and severity of headache will be registered. At the end of treatment and after the registration of patient information, codes will be unveiled.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamedan University of Medical Science

Street address

School of Medicine, Shahid Fahmide Blvd. Pazhuhesh Crossroad

City

Hamedan

Postal code

Approval date

2013-09-10, 1392/06/19

Ethics committee reference number

16/35/9/1693/د/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 after three months of treatment

Method of measurement

Asking from patient

2

Description

Severity of headache

Timepoint

Before and after three months of treatment

Method of measurement

Asking from patient

3

Description

Pediatric Migraine Disability Grade (pedMIDAS)

Timepoint

Before and after three months of treatment

Method of measurement

Asking from patient

4

Description

Clinical general impression

Timepoint

Before and after three months of treatment

Method of measurement

Asking from patient

Secondary outcomes

1

Description

Omega-3 side effects including gastrointestinal side effects and allergy

Timepoint

Monthly until three months of treatment

Method of measurement
Clinical exam and asking from patients

Intervention groups

1

Description
Twenty mg/kg/day valproate sodium daily in 2 divided doses with one omega-3 capsule contain of 1 gr fish oil, Produced by Zahravi Pharmaceutical Company, for 3 months (intervention)
Category
Treatment - Drugs

2

Description
Twenty mg/kg/day valproate sodium daily in 2 divided doses with one placebo capsule (as the same color, package, and shape as omega-3 capsule without any active ingredient, Produced by Zahravi Pharmaceutical Company) for 3 months (control)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Clinic
Full name of responsible person
Afshin Fayyazi
Street address
Imam Khomeini Clinic, Mirzade Eshghi St.
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2

Recruitment center
Name of recruitment center
Pediatric Neurology Clinic of Besat Hospital
Full name of responsible person
Afshin Fayyazi
Street address
Besat Hospital, Shahid Motahari Blvd. Resalat Sq.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Hamedan University of Medical Science
Full name of responsible person
Saeed Bashiriyan
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Vice Chancellor for Research and Technology, Hamedan University of Medical Science, Shahid Fahmide Blvd. Pazhuhesh Crossroad
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology, Hamedan University of Medical Science
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
Hamedan University of Medical Science, School of Medicine
Full name of responsible person
Afshin Fayyazi
Position
Pediatric Neurologist/Assistant Professor
Other areas of specialty/work
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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