Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of omega 3 fatty acid supplementation in children with refractory epilepsy refer to selected Isfahan's hospitals 1389

Protocol summary

Summary

It has been shown that administration of fatty acids to laboratory animals reduces seizure frequency but there is not enough information in humans and especially in children.The objective of this study was to investigate the efficacy of Omega 3 in children with refractory epilepsy. This randomized crossover open label non placebo controlled phase 3 clinical trial was conducted in two medical centers in two three month periods. Subjects of the study were children (2-13 years old) who referred to neurology outpatient clinics of the two medical centers and were diagnosed with refractory epilepsy by a pediatric neurologist.The inclusion criteria consisted of presence of at least 4 convulsions per month which were not controlled by at least 3 different anti-epileptic medications.The exclusion criterion was allergy to the fish oil.The subjects were randomly divided into two groups.The first group received 1.5 grams/m2 of Omega 3 in a single daily dose for the first three months in addition to their routine anti-epileptic medications.The second group only received their routine anti-epileptic medications.At the end of three month period, each group underwent a one month washout period and then got crossed over with respect to treatment. Parents were asked to report their observations of frequency and severity of seizures in specific forms designed by the investigators.At the end of each three month period, the researchers reviewed daily logs provided by the parents and the average number and severity of seizures were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012115365N1**
Registration date: **2011-08-08, 1390/05/17**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-08-08, 1390/05/17

Registrant information

Name

Hamed Azarnoush

Name of organization / entity

Islamic Azad university of Najafabad

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad University of Medical Sciences Najafabad Branch

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of omega 3 fatty acid supplementation in children with refractory epilepsy refer to selected Isfahan's hospitals 1389

Public title

Assess the effectiveness of omega 3 on children with refractory epilepsy

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria:lack of neurodegenerative disorder; lack of neurometabolic disorder; Insufficient control of epilepsy by at least 3 anti epileptic medications; More than 4 seizure episodes per month. Exclusion Criteria: exhibit frequent vomiting; inability to swallow; an allergy to fish oil; subjects taking high doses of aspirin (>325mg daily)
Age
From **2 years** old to **13 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjrib street
City
Isfahan
Postal code
81745-319
Approval date
2011-07-12, 1390/04/21
Ethics committee reference number
490001

Health conditions studied

1

Description of health condition studied
Epilepsy
ICD-10 code
G40.1,G40.
ICD-10 code description
Localization-related (focal)(partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset Benign childhood epilepsy with centrotemporal EEG spikes Childhood epilepsy with occipital EEG paroxysms G40.1 Localization-related (foca

Primary outcomes

1

Description
Frequency of seizures
Timepoint
baseline; after first three month period; after second three month period
Method of measurement
Average of seizure episodes at the end of each three month period

2

Description
Severity of seizure
Timepoint
baseline; after first three month period; after second three month period
Method of measurement
scale of 1 - 10, scored by parents

Secondary outcomes

1

Description
other benefits of omega3
Timepoint
after three month period of receiving omega 3
Method of measurement
interview

Intervention groups

1

Description
Group 1:In the first three months group 1 received 1.5 grams/m2 of Omega 3 in a single daily dose in addition to their routine anti-epileptic medications.Each 5 ml of the Omega 3 contained 1.484 mg of omega 3, 786 mg of EPA and 524 mg of DHA.After one month washout period this group received only their routine anti-epileptic medications for another three months.During the study period, the-anti epileptic medication or its dosage could be changed if investigators determined a need for this change.
Category
Treatment - Drugs

2

Description
Group 2: In the first three months group 2 received only their routine anti-epileptic medications. For the second three month this group received 1.5 grams/m2 of Omega 3 in a single daily dose in addition to their routine anti-epileptic medications.Each ml of the Omega 3 contained 1.484 mg of omega 3, 786 mg of EPA and 524 mg of DHA. During the study period, the-anti epileptic medication or its dosage could be changed if investigators determined a need for this change.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Zahra Hospital
Full name of responsible person
Dr Mohammadreza Ghazavi
Street address
Al Zahra Hospital, Soffeh street, Hakimnezami junction
City
Isfahan

2

Recruitment center
Name of recruitment center
Dr Shariati Hospital
Full name of responsible person
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Dr Shariati Hospital, Chaharbagh bala street, Darvaze Shiraz square
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Islamic Azad University of Medical Sciences Najafabad Branch
Full name of responsible person
Dr.Reza Ebrahimi
Street address
Islamic Azad University of Najafabad, Daneshgah blvd
City
Najafabad

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, Islamic Azad University of Medical Sciences Najafabad Branch

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
Islamic Azad University of Najafabad
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Dr. Hamed Azarnoush
Position
Intern-Medical student
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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