

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 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)

###### Phone

+98 33 1229 1111

###### Email address

hamedmds@smd.iaun.ac.ir

##### 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 committee 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

Dr. Hamed Azarnoush

##### Street address

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

#### Full name of responsible person

Dr. Hamed Azarnoush

#### Position

Intern-Medical student

#### Other areas of specialty/work

#### Street address

Islamic Azad University of Najafabad, Daneshgah blvd

#### City

Najafabad

#### Postal code

517

#### Phone

+98 33 1229 1111

#### Fax

+98 31 1630 2998

#### Email

hamedmds@yahoo.com, hamedmds@gmail.com

#### Web page address

www.iaun.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Saadatnia

#### Position

Neurologist

#### Other areas of specialty/work

#### Street address

Isfahan University of Medical Sciences, Hezarjrib street

#### City

Isfahan

#### Postal code

#### Phone

+98 31 1668 0048

#### Fax

+98 31 1668 5145

#### Email

saadatnia@med.mui.ac.ir

**Web page address**

www.mui.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University of Najafabad

**Full name of responsible person**

Dr. Hamed Azarnoush

**Position**

Intern-medical student

**Other areas of specialty/work**

**Street address**

Islamic Azad University of Najafabad, Daneshgah blvd

**City**

Najafabad

**Postal code**

517

**Phone**

+98 33 1229 1111

**Fax**

+98 31 1630 2998

**Email**

hamedmds@yahoo.com, hamedmds@smd.iaun.ac.ir

**Web page address**

www.iaun.ac.ir

**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*