

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Effect of omega-3 versus placebo on the clinical and paraclinical situation in patients with refractory epilepsy: a triple blind randomized clinical trial

#### Protocol summary

##### Summary

**Objectives:** To assess the effect of omega-3 versus placebo on the clinical and paraclinical situation in patients with refractory epilepsy. **Design:** a triple blind randomized clinical trial. **Setting and conduct:** The eligible patients with refractory epilepsy who will refer to farshchian Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** (a) age of 18 to 55 years; (b) having refractory epilepsy. **Exclusion criteria:** (a) pregnancy or breastfeeding; (b) having underlying diseases such as liver disease, kidney disease, active infection, pulmonary disease, hypertension, dementia, and mental retardation; (c) catamenial epilepsy. **Intervention group:** Routine treatment plus oral omega-3 one tablet 1000 mg twice a day for 4 months. **Control group:** Routine treatment plus a placebo tablet twice a day for 4 months. **Primary outcome:** Assessing the frequency of seizures before treatment and every month for 4 months by taking history. **Secondary outcome:** (a) assessing serum level of interleukin-6 before treatment and 4 months later by laboratory test; (b) assessing serum level of TNF- $\alpha$  before treatment and 4 months later by laboratory test; (c) assessing electroencephalogram changes before treatment and 4 months later by taking electroencephalogram. **Randomization:** The patients will be randomly assigned to intervention and control groups using block randomization of six. **Blinding:** Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201604179014N96**

Registration date: **2016-04-26, 1395/02/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-04-26, 1395/02/07

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2015-09-11, 1394/06/20

##### Expected recruitment end date

2015-12-09, 1394/09/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of omega-3 versus placebo on the clinical and paraclinical situation in patients with refractory epilepsy:

a triple blind randomized clinical trial

## Public title

Effect of omega-3 versus placebo on the clinical and paraclinical situation in patients with refractory epilepsy

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 18 to 55 years; (b) having refractory epilepsy. Exclusion criteria: (a) pregnancy or breastfeeding; (b) having underlying diseases such as liver disease, kidney disease, active infection, pulmonary disease, hypertension, dementia, and mental retardation; (c) catamenial epilepsy.

## Age

From **18 years** old to **55 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of six. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

## Postal code

6517838695

## Approval date

2016-01-10, 1394/10/20

## Ethics committee reference number

IR.UMSHA.REC.1394.456

## Health conditions studied

### 1

#### Description of health condition studied

Refractory epilepsy

#### ICD-10 code

G40

#### ICD-10 code description

Epilepsy

## Primary outcomes

### 1

#### Description

Assessing the frequency of seizures

#### Timepoint

before treatment and every month for 4 months

#### Method of measurement

by taking history

## Secondary outcomes

### 1

#### Description

assessing serum level of interleukin-6

#### Timepoint

before treatment and 4 months later

#### Method of measurement

by laboratory test

### 2

#### Description

assessing serum level of TNF- $\alpha$

#### Timepoint

before treatment and 4 months later

#### Method of measurement

by laboratory test

### 3

#### Description

assessing electroencephalogram changes

#### Timepoint

before treatment and 4 months later

#### Method of measurement

by taking electroencephalogram

## Intervention groups

## 1

### Description

Routine treatment plus oral omega-3 one tablet 1000 mg twice a day for 4 months

### Category

Treatment - Drugs

## 2

### Description

Routine treatment plus a placebo tablet twice a day for 4 months

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farshchian Hospital

##### Full name of responsible person

Dr Shaghayegh Omrani

##### Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

#### 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 the Technology, Hamadan  
University of Medical Sciences

#### 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

Farshchian Hospital

#### Full name of responsible person

Dr Shaghayegh Omrani

#### Position

Resident of Neurology

#### Other areas of specialty/work

#### Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

#### City

Hamadan

#### Postal code

#### Phone

+98 81 3827 4184

#### Fax

#### Email

drshaghayeghomrani@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Farshchian Hospital

#### Full name of responsible person

Dr Mehrdokht Mazdeh

#### Position

Neurologist

#### Other areas of specialty/work

#### Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

#### City

Hamadan

#### Postal code

#### Phone

+98 81 3827 4184

#### Fax

#### Email

mehrdokhtmazdeh@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Department of Epidemiology

#### Full name of responsible person

Dr Jalal Poorolajal

#### Position

Associate Professor

#### Other areas of specialty/work

#### Street address

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

#### City

Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0090  
**Fax**  
**Email**  
poorolajal@umsha.ac.ir  
**Web page address**

## 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*