

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- α 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)

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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- α

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

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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

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

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Person responsible for scientific inquiries

Contact

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Farshchian Hospital

Full name of responsible person

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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

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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