

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The effect of omega-3 versus placebo on the clinical and paraclinical signs and symptoms of drug-resistant epileptic patients: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: Omega-3 as a polyunsaturated fatty acid has anti-inflammatory effects. In previous studies, it has been demonstrated that the frequency of seizures, associated with some of inflammatory factors. So we decided to study the effects of omega-3 on the symptoms and inflammatory markers in patients with refractory drug resistant epilepsy. Design: This study is a triple-blind clinical trial which will be carried out on 40 patients with refractory epilepsy. Setting and conduct: Patients were randomly divided into two groups of 20 people. At the beginning and at the end of treatment protocol, 5 ml blood sample per patient is taken and the level of inflammatory factors TNF- α and IL-6 in their blood serum will be measured by ELISA. During the study, also frequency and intervals of epileptic attacks will be recorded. Participants including major eligibility criteria: Inclusion criteria: generalized epilepsy resistant to treatment: 18 to 65 years Exclusion criteria: Catamenial epilepsy; Patients with impaired renal function ... Intervention: The test group will receive (600 mg twice a day) omega-3 as a adjuvant therapy in the treatment. The control group also will receive placebo twice daily (Placebo is made by Zahravi pharmaceutical company) for a period of 4 months as a test group (It should be noted that patients do not consume omega-3 drug one week per month). main outcome measures (variables): It is clear that the primary outcome variable is the frequency of seizures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062922142N2**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Mehrdokht Mazdeh

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research and technology Hamadan university of medical sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 versus placebo on the clinical and paraclinical signs and symptoms of drug-resistant epileptic patients: a triple blind randomized clinical trial

Public title

The effect of omega-3 on drug resistant epilepsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: drug resistant epilepsy; 18 to 65 years old. Exclusion criteria: patients with impaired renal function; patients with catamenial seizure; Patients with hepatic dysfunction; Patients with active infection; Patients with brain or mental dysfunction; Patients who can not take oral medication; Patients treated with anti-inflammatory or antioxidant drugs in the past month; patients with other concurrent inflammatory disease; Patients who can not tolerate the side effects; Patients who are pregnant or lactating

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan university of medical sciences, Ethics Committee

Street address

Floor2, Faculty of Medicine, Shahid Fahmideh St, Pajuhesh Sq

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Approval date

2015-07-16, 1394/04/25

Ethics committee reference number

IR.UMSHA.REC.1394.263

Health conditions studied

1

Description of health condition studied

epilepsy

ICD-10 code

G40.3

ICD-10 code description

Nonspecific epileptic seizures:•atonic

Primary outcomes

1

Description

The frequency of attacks

Timepoint

Up to 4 months after the start treatment

Method of measurement

Quantitatively

Secondary outcomes

1

Description

IL-6

Timepoint

Before the intervention-4 months after the treatment

Method of measurement

pg per ml by ELISA

2

Description

TNF- α

Timepoint

Before the intervention-4 months after the treatment

Method of measurement

pg per ml by ELISA

Intervention groups

1

Description

Standard treatment plus 300 mg (one tablet) omega-3 twice a day orally for 4 months

Category

Treatment - Drugs

2

Description

Standard treatment plus a placebo tablet twice daily orally for 4 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian hospital

Full name of responsible person

Dr Mehrdokht Mazdeh

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Imam khomeini clinic, Mirzade Eeshghi St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

hamadan university of medical sciences, Vice-chancellor for research and technology , Hamedan

Full name of responsible person

Dr. Rasool Hadadi

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Floor2, Faculty of Medicine, Shahid Fahmideh St, Pajuhesh Sq

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Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

hamadan university of medical sciences, Vice-chancellor for research and technology , Hamedan

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

Hamadan university of medical sciences, Faculty of pharmacy

Full name of responsible person

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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