Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effect of eicosapentaenoic acid and docosahexaenoic acid on the treatment of depression

Protocol summary

Summary

The aim of this study was comparing the effect of eicosapentaenoic acid and docosahexaenoic acid on the treatment of depression in 81 mild to moderately depressed outpatients referring to Bahman psychiatry clinic in Yazd (Iran). After obtaining informed consent, the patients were randomized into three groups receiving eicosapentaenoic acid, docosahexaenoic acid, or placebo supplements using table of random numbers. The patients received eicosapentaenoic acid 1 g/day, docosahexaenoic acid, 0.93 g/day, or coconut oil (as placebo), 1 g/day for 12 weeks in the winter of 2011. Our primary outcome was severity of depression which was assessed with clinical interview by a psychiatrist at the study entry and weeks 6 and 12 by using HRSD.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010054873N1**
Registration date: **2011-07-03, 1390/04/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-03, 1390/04/12

Registrant information

Name

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Name of organization / entity

Yazd University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Shahid Sadughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2010-08-16, 1389/05/25

Expected recruitment end date

2011-04-20, 1390/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of eicosapentaenoic acid and docosahexaenoic acid on the treatment of depression

Public title

Comparison of the effect of eicosapentaenoic acid and docosahexaenoic acid on the treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ages between 18-75 years; a Beck Depression Inventory II score of 10-28; a Hamilton Rating Scale for Depression score of 8-18; no changes in doses or types of antidepressant medications within 4 weeks prior to the study entry; diagnose of mild to moderate depression with structured clinical interview by a psychiatrist according to DSM-IV-TR criteria Exclusion criteria: diagnosis of any co-morbid mental disorder other than depression, serious suicidal or homicidal thoughts; use of fish oil or omega, supplements within the last 6 months or having taken more than 3 servings per weeks of fish; any changes in doses or types of current antidepressant medications within study period

or use of psychotropics, anticonvulsants, mood stabilizers, and anticoagulants; cupping or blood coagulation disorders, gastrointestinal absorption disorders, and eating disorders; allergy to sea foods or study drugs, and history of multiple adverse drug reactions; history of electroconvulsive therapy or severe medical disorders that may lead in depression including cardiovascular, hepatic, renal, respiratory, and endocrine diseases; smoking and drug or alcohol abuse; pregnancy or breastfeeding; serious adverse effects and incompliance to study protocol

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **81**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadughi University of Medical Sciences

Street address
Central Organization of Shahid Sadughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City
Yazd

Postal code
8916978477

Approval date
2010-07-20, 1389/04/29

Ethics committee reference number
41170/1/17/پ

Health conditions studied

1

Description of health condition studied
Recurrent depressive disorder

ICD-10 code
F33

ICD-10 code description
Recurrent depressive disorder

Primary outcomes

1

Description
Severity of depression

Timepoint
Weeks 0, 6, and 12

Method of measurement
Hamilton Rating Scale for Depression

Secondary outcomes

1

Description
Remission

Timepoint
Week 12

Method of measurement
Hamilton Rating Scale for Depression

Intervention groups

1

Description
Control group: receiving coconut oil 1000 mg/day (2 oral capsules) for 12 weeks

Category
Placebo

2

Description
First intervention group: receiving eicosapentaenoic acid 1000 mg/day (2 oral capsules) for 12 weeks

Category
Treatment - Drugs

3

Description
Second intervention group: receiving docosahexaenoic acid 930 mg/day (2 oral capsules) for 12 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bahman Psychiatry Clinic

Full name of responsible person
Dr. Seyed Mojtaba Yassini Ardakani
Street address
Bahman Psychiatry Clinic, Kashani Street, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Accessory of Shahid Sadughi University of Medical Sciences
Full name of responsible person
Dr. Hasan Mozaffari Khosravi
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Central Organization of Shahid Sadughi University of Medical Sciences, Bahonar Square, Yazd, Iran
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Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Accessory of Shahid Sadughi 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

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Person responsible for updating data

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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