

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of omega-3-fatty acids versus placebo on clinical symptoms of patients with major depressive disorder: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of omega-3-fatty acids versus placebo on clinical symptoms of patients with major depressive disorder. Design: A double blind randomized clinical trial. Setting and conduct: The eligible patients with major depressive disorder who will refer to Sina Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 65 years; major depressive disorder Exclusion criteria: Pregnancy or breastfeeding; narcotic addiction; psychosis. Intervention group: Routine treatment plus omega-3 capsule 100 mg daily for 12 weeks. Control group: Routine treatment plus placebo capsule daily for 12 weeks Primary outcome: (a) depressive symptoms using standard questionnaire before intervention and 6 and 12 weeks after intervention; (b) sleep disorder using standard questionnaire before intervention and 6 and 12 weeks after intervention; (c) social competencies using standard questionnaire before intervention and 6 and 12 weeks after intervention; (d) physical activity using standard questionnaire before intervention and 6 and 12 weeks after intervention; (e) cognitive performance using standard questionnaire before intervention and 6 and 12 weeks after intervention. Randomization: Random assignment of the patients to the intervention and control groups using random number table. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705249014N164**
Registration date: **2017-06-08, 1396/03/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-08, 1396/03/18

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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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

2017-06-22, 1396/04/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega-3-fatty acids versus placebo on clinical

symptoms of patients with major depressive disorder: a double blind randomized clinical trial

Public title

Effect of omega-3-fatty acids versus placebo on clinical symptoms of patients with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 65 years; major depressive disorder Exclusion criteria: Pregnancy or breastfeeding; narcotic addiction; psychosis.

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups using random number table. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double 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

2017-04-08, 1396/01/19

Ethics committee reference number

IR.UMSHA.REC.1396.10

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32.2

ICD-10 code description

Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description

depressive symptoms

Timepoint

before intervention and 6 and 12 weeks after intervention

Method of measurement

using standard questionnaire

2

Description

sleep disorder

Timepoint

before intervention and 6 and 12 weeks after intervention

Method of measurement

using standard questionnaire

3

Description

social competencies

Timepoint

before intervention and 6 and 12 weeks after intervention

Method of measurement

using standard questionnaire

4

Description

physical activity

Timepoint

before intervention and 6 and 12 weeks after intervention

Method of measurement

using standard questionnaire

5

Description

cognitive performance

Timepoint

before intervention and 6 and 12 weeks after

intervention
Method of measurement
using standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus omega-3 capsule 100 mg daily for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus placebo capsule daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Ali Sadeghi

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
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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 and 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

Sina Hospital

Full name of responsible person

Dr Ali Sadeghi

Position

Resident of Psychology

Other areas of specialty/work

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Person responsible for updating data

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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