

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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

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 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

##### 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 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

##### Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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+98 81 3827 4184

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Sina Hospital

##### Full name of responsible person

Dr Mohammad Haghghi

##### Position

Psychologist

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## 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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**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*