# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 2026

## The Effect of Adding Non-saturated Fatty Acid Omega 3 and Placebo on anti-Depressant Drugs among Patients with Depression Disorder

### Protocol summary

**Study aim**

The Effect of Adding Non-saturated Fatty Acid Omega 3 and Placebo on anti-Depressant Drugs among Patients with Depression Disorder

**Design**

randomised, blinded, controlled clinical trial with a parallel group

**Settings and conduct**

Patients were first evaluated by the Beck Test . Finally, the participants with a score of over 13 were selected. The patients were divided randomly into two groups of 30,The two groups were the same with respect to antidepressant. In the two groups, in addition to specific serotonin reuptake inhibitors, omega- 3s was given at a daily dose of 300-600 mg. In the control group, in addition to specific inhibitors of serotonin reuptake, a placebo was prescribed. The two groups were analyzed in weeks 0, 2 , 4 , 6 and 8 so that the researchers could assess the level of depression and functional testing based on the Beck Test.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: age ranging from 18- 65years, major depressive disorder based on DSM-IV Index confirmed by a psychiatrist. Exclusion criteria: incorporated bipolar disorder and other psychiatric disorders, drug or alcohol consumption during the research, dependence or history of drug or alcohol in 6 recent months, history of allergy to serotonin reuptake inhibitors or omega- 3fatty acids , history of seizure, pregnancy, active suicidal thoughts and homicide, chronic physical disease , use of anticoagulants and medications that interfere with omega- 3 intake

**Intervention groups**

one group was given selective serotonin reuptake inhibitors plus omega-3 fatty acids and other group received selective serotonin reuptake inhibitors in addition to placebo.

**Main outcome variables**

Severity of depression

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201125049487N1**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **retrospective**

Last update: **2020-12-22, 1399/10/02**
Update count: **0**

**Registration date**

2020-12-22, 1399/10/02

**Registrant information**

**Name**

Sara Behbahani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 61 3416 2202

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farahmand.karen@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2016-05-21, 1395/03/01

**Expected recruitment end date**

2016-08-20, 1395/05/30

**Actual recruitment start date**

2016-05-21, 1395/03/01

**Actual recruitment end date**

2016-08-20, 1395/05/30

**Trial completion date**

2016-10-21, 1395/07/30

**Scientific title**

The Effect of Adding Non-saturated Fatty Acid Omega 3 and Placebo on anti-Depressant Drugs among Patients with Depression Disorder

**Public title**
Effect of Omega3 in depression
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patient with major depressive disorder who had been to the psychiatric clinic of Golestan. Age witbeen 18-65 years
**Exclusion criteria:**
Bipolar disorder and other psychiatric disorders Drug or alcohol consumption during the research, dependence or history of drug or alcohol in 6 recent months, History of allergy to serotonin reuptake inhibitors or omega- 3fatty acids History of seizure Pregnancy Active suicidal thoughts and homicide Use of anticoagulants and medications that interfere with omega- 3 intake (such as anti-platelet drugs such as aspirin and enoxaparin and heparin and warfarin) chronic physical disease ( blood pressure, diabetes, heart disease, liver and kidney disease )
**Age**
From **18 days** old to **65 days** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **60**
Actual sample size reached: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization was according to permutation block with size of 4 with toss a coin divided randomly into two equal groups of people.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Blindness was according to the fact that which the patients did not know what type of drug they received. The capsule of omega- 3 fatty acids and placebo were exactly in the same shape, color, smell and taste.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of ahwaz University of Medical Science
**Street address**
Golestan Blvd, ahwaz University of Medical Science
**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
٦١٣٦٨٣٥٦٨٥
**Approval date**
2016-07-09, 1395/04/19
**Ethics committee reference number**
IR.AJUMS.REC.1395.234

## Health conditions studied

### 1

**Description of health condition studied**
Major depressive disorder
**ICD-10 code**
F33.2
**ICD-10 code description**
Major depressive disorder, recurrent severe without psychotic features

## Primary outcomes

### 1

**Description**
Depression values in beck test
**Timepoint**
From the start of treatment and week 2,4,6,8
**Method of measurement**
Beck test

## Secondary outcomes

### 1

**Description**
Dose of SSRI
**Timepoint**
At the beginning of treatment and week 2,4,6,8 after tratment started
**Method of measurement**
Evaluation of drug used based of patient file

## Intervention groups

### 1

**Description**

Control group: control group with 30 patients that received special serotonin reuptake inhibitors ( fluvoxine20-80 mg or citalopram 20-40, or sertraline with congestion 50-200 mg ) in addition to a placebo(.Empty jelly capsul that made in the pharmacy school of jundishapur university) this group was tested at weeks 0, 2, 4, 6 and 8 in order to evaluate depression and functional status through Beck Test.

**Category**

Placebo

**2**

**Description**

One group with 30 patients which was received special serotonin reuptake inhibitors ( fluvoxine20-80 mg or citalopram 20-40, or sertraline with congestion 50-200 mg ) in addition to omega- 3 fatty acid 300-600mg per day in the form of peal omega3 zahravi company for 8 weeks, were tested at weeks 0, 2, 4, 6 and 8 in order to evaluate depression and functional status through Beck Test.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Golestan hospital
**Full name of responsible person**
Maasome nazari nasab
**Street address**
Golestan Blvd, golestan hospital
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masomenazari@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Sara behbahani
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Farahmand.karen@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Individual
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Persons

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Maasome nazari nasab
**Position**
Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Psychiatrics
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**
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**Latest degree**
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**Other areas of specialty/work**
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**Email**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Not applicable

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Not applicable

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable