

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the efficacy of omega-3 as an adjunctive therapy of sertraline and venlafaxine in improving symptoms of major depressive disorder : A Double-blind , placebo controlled trial

#### Protocol summary

##### Study aim

Determining the effectiveness of omega-3 combination therapy with sertraline and venlafaxine on the symptoms of major depressive disorder

##### Design

Double-blind clinical trial, with two intervention groups and two control groups, randomized

##### Settings and conduct

They are randomly divided into four groups of 16 people. The first group is a combination of 25 mg of sertraline daily for the first 4 days and then 50 mg daily to complete the course of treatment with one gram of omega-3 daily, the second group 37.5 ml. Warm venlafaxine daily for the first 4 days and then 70 mg daily to complete the course of treatment with one gram of omega-3 daily, the third group 25 mg of sertraline daily for the first 4 days and then 50 mg daily to complete the course of treatment with The placebo and the fourth group combine 37.5 mg of venlafaxine daily for the first 4 days and then 70 mg daily until single. They will use the course of treatment with placebo. They are tested by Hamilton's questionnaire before and 4 weeks after treatment and demographic information is collected. All stages of the study will be performed in the psychiatric clinic of Imam Hossein Hospital.

##### Participants/Inclusion and exclusion criteria

Having DSM-V diagnostic criteria for major depressive disorder with clinical diagnosis of psychiatrist Earning a score higher than 7 based on Hamilton's Questionnaire (HAM-D) Obtain informed consent from the patient Age between 18 and 60 years There is no psycho-manifestation

##### Intervention groups

Group 1: Receive 50 mg sertraline + 2 gr of omega-3  
Group 2: Receive 75 mg venlafaxine + 2 gr of omega-3  
Group 3: Receive 50 mg sertraline + placebo  
Group 4: Receive 75 mg venlafaxine + placebo

#### Main outcome variables

Fatigue ; Feelings of guilt ; Insomnia ; Irritability ;  
Appetite change ; Anhedonia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190302042885N1**

Registration date: **2020-04-20, 1399/02/01**

Registration timing: **retrospective**

Last update: **2020-04-20, 1399/02/01**

Update count: **0**

##### Registration date

2020-04-20, 1399/02/01

##### Registrant information

##### Name

Mohammad Ahadi fard moghadam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3677 3900

##### Email address

mohammadafm72@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of omega-3 as an adjunctive therapy of sertraline and venlafaxine in improving symptoms of major depressive disorder : A Double-blind , placebo controlled trial

**Public title**

omega3 in depression

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having DSM-V diagnostic criteria for major depressive disorder with clinical diagnosis of psychiatrist Earning a score higher than 7 based on Hamilton's Questionnaire (HAM-D) Obtain informed consent from the patient Age between 18 and 60 years There is no psycho-manifestation

**Exclusion criteria:**

Drug abuse and drug abuse other than nicotine and caffeine IQ less than 70 There is another psychiatric disorder in the diagnostic axis one The presence of a medical condition (especially liver disease, cardiovascular disease and hypertension) or significant neurology

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After completing the course of treatment and recording the results, matching the delivery codes and the patient's specific code is determined by what treatment the patient received.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will be referred to a designated pharmacy after an examination by a psychiatrist and will receive information and receive a specific code, and will be randomized by the provider of the medication, placebo or pills containing omega-3s. After completing the course of treatment and recording the results, matching the delivery codes and the patient's specific code is determined by what treatment the patient received. The patient and psychiatrist are not on the verge of being given a placebo or an effective pill

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

**Street address**

Deputy of Research and Technology, Alley Safariyan, 45 meters Golshahr, Karaj, Alborz Province

**City**

Karaj

**Province**

Alborz

**Postal code**

3198764653

**Approval date**

2019-01-14, 1397/10/24

**Ethics committee reference number**

IR.ABZUMS.REC.1397.162

**Health conditions studied****1****Description of health condition studied**

Major Depression

**ICD-10 code**

F32.9

**ICD-10 code description**

Depression NOS Depressive disorder NOS

**Primary outcomes****1****Description**

Hamilton questionnaire score

**Timepoint**

Before treatment and 4 weeks after treatment

**Method of measurement**

Hamilton questionnaire

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: 50 mg Sertraline daily plus two grams of Omega 3 daily

### Category

Treatment - Drugs

## 2

### Description

Intervention group: 75 mg of venlafaxine daily plus two grams of omega 3 daily

### Category

Treatment - Drugs

## 3

### Description

Control group:50 mg sertraline daily with placebo

### Category

Placebo

## 4

### Description

Control group: 75 mg daily venlafaxine with placebo

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Hossein Hospital

#### Full name of responsible person

Mohammad Ahadi Fard Moghadam

#### Street address

104 Street,Mohammad shahr,

#### City

Karaj

#### Province

Alborz

#### Postal code

4356968526

#### Phone

+98 26 3622 0118

#### Email

Imamhosseinhospital@abzums.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Alborz Univesity of Medical Science

#### Full name of responsible person

Shahroz Yazdani

#### Street address

No7 , Safae ave , 45m Golshar steer

### City

Karaj

### Province

Alborz

### Postal code

2365987456

### Phone

+98 26 3622 0118

### Email

reserach@abzums.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Alborz Univesity of Medical Science

### Proportion provided by this source

50

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Alborz Univesity of Medical Science

#### Full name of responsible person

Mohammad Ahadi Fard Moghadam

#### Position

Medical student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Psychiatrics

#### Street address

Alborz university of medical science,Boo Ali street,karaj

#### City

Karaj

#### Province

Alborz

#### Postal code

1234567895

#### Phone

+98 26 3677 3900

#### Fax

#### Email

mohammadafm72@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Alborz University of Medical science

**Full name of responsible person**

Mohammad Ahadi Fard Moghadam

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Alborz university of medical science,Boo Ali street,karaj

**City**

Karaj

**Province**

Alborz

**Postal code**

1234567895

**Phone**

+98 26 3677 3900

**Fax**

**Email**

mohammadafm72@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Mohammad Ahadi Fard Moghadam

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Alborz University of Medical science,Boo Ali street,karaj

**City**

Karaj

**Province**

Alborz

**Postal code**

1234567895

**Phone**

+98 26 3677 3900

**Fax**

**Email**

mohammadafm72@gmail.com

**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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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