

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of omega-3 supplementation on serum total antioxidant capacity, superoxide dismutase and catalase in bipolar patients

Protocol summary

Study aim

Determining the effect of omega-3 supplementation on serum levels of total antioxidant capacity, superoxide dismutase, and catalase in bipolar patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 56 patients.

Settings and conduct

The study will be conducted on 56 patients with bipolar disorder in depressed phase who have been ill for at least 6 months. Eligible individuals will be randomly divided into two groups. In addition to their usual treatment, one group will receive 2 gr omega-3 supplement for 8 weeks and the other group or control group will receive their usual placebo for 8 weeks. Double blinding method is used. A person who is responsible for giving supplements and the intervention and the technician responsible for recording the consequences will not be aware the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1)The involvement with bipolar disease 2)16-50 years of age 3)Patients with minimum six months after onset of disease. 4)Informed and freely consent for participation in study. 5)The lack of receiving omega-3 supplement several months before of participation in the study. 6)The lack of programmed surgery in three months future and consumption of drugs interfering with omega-3. 7)The lack of high blood pressure and consumption of alcohol and drugs. Exclusion criteria 1)Change in drug dose and type. 2)Reactivity against omega-3 3)The consumption of lesser than 80% supplement. 4)Having inflammation and infectious diseases. 5)Withdrawal of the study for any reason.

Intervention groups

Intervention group:30 patients with bipolar disorder who received omega-3 supplement. Control group:30 patients with bipolar disorder receiving a placebo containing edible paraffin oil.

Main outcome variables

Means of total antioxidant capacity, superoxide dismutase, and catalase

General information

Reason for update

Termination of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20211220053469N2**

Registration date: **2022-02-12, 1400/11/23**

Registration timing: **prospective**

Last update: **2022-04-26, 1401/02/06**

Update count: **2**

Registration date

2022-02-12, 1400/11/23

Registrant information

Name

Hadi Eslahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3348 4862

Email address

hadi_eslahi2015@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-04-30, 1401/02/10

Actual recruitment start date

2022-02-13, 1400/11/24

Actual recruitment end date

2022-02-17, 1400/11/28

Trial completion date

2022-04-09, 1401/01/20

Scientific title

The effect of omega-3 supplementation on serum total antioxidant capacity, superoxide dismutase and catalase in bipolar patients

Public title

The effect of omega-3 supplementation on serum total antioxidant capacity, superoxide dismutase and catalase in bipolar patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The involvement with bipolar disease Patients with minimum six months after onset of disease Informed and freely consent for participation in the design by patient and family members. The lack of receiving omega-3 supplement several months before of participation in the study The lack of programmed surgery in three months future The lack of consumption of drugs interfering with omega-3 such as anticoagulant drugs The lack of high blood pressure The lack of alcohol and drugs

Exclusion criteria:

The change in drug dose and type Sensitive reaction against omega-3 The consumption of lesser than 80% supplement The involvement with inflammatory and infectious diseases Withdrawal of the study for any reason

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **56**

Actual sample size reached: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients is conducted based on permuted block stratified randomization. The patients are classed based on age and gender. The patients are randomly selected based on quadruplet blocks (two groups A & B and two replications for each group). The blocks are designed by help of R software (version of 4.02)

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinding is used in the current study, so that person giving supplements and intervention, technician responsible for registration will not be informed study

details.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Zahedan University of Medical Sciences

Street address

Islamic Republic Boulevard, 18 meters Golha Street, Golha 3, Milan 2, right, second side, left

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816993353

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

IR.ZAUMS.REC.1400.381

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

Bipolar disorder

ICD-10 code

F31.3

ICD-10 code description

Bipolar disorder, current episode depressed, mild or moderate severity

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

Mean of total antioxidant capacity

Timepoint

At the beginning of the study (before the intervention) and 60 days after the start of omega-3 supplementation

Method of measurement

Commercial Kit / ELISA

2**Description**

Mean of superoxide dismutase

Timepoint

At the beginning of the study (before the intervention) and 60 days after the start of omega-3 supplementation

Method of measurement
Commercial Kit / ELISA

3

Description

Mean of catalase

Timepoint

At the beginning of the study (before the intervention) and 60 days after the start of omega-3 supplementation

Method of measurement

Commercial Kit / ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 28 patients with bipolar disorder, in addition to their usual treatment, will receive 2 omega 3 capsules daily (made by Barij Pharmaceutical Company), each capsule containing 1 gram of omega 3, for 8 weeks, which is recommended to be taken with lunch and dinner.

Category

Rehabilitation

2

Description

Control group: 28 patients with bipolar disorder, in addition to their usual treatment, will receive 2 placebo capsules containing edible paraffin oil (made by Barij Pharmaceutical Company) , each capsule containing 1 gram of edible paraffin oil, for 8 weeks, which is recommended to be taken with lunch and dinner.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan hospital

Full name of responsible person

Azizullah Mujahed

Street address

Imam Khomeini St.,in front of the Grain Department

City

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Sistan-va-Balouchestan

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9813913777

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Email

baharanhospital@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

Street address

Zahedan, Dr. Hesabi Square, Campus of University of Medical Sciences, Vice Chancellor for Research and Technology, Student Scientific Research Center

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Msrc@zamus.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

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

Zahedan University of Medical Sciences

Full name of responsible person

Hadi Eslahi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Islamic Republic Boulevard., 18 meters Golha Street.,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Hadi Eslahi

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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

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