Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The assessment of the effect of omega-3 supplementation on serum interleukin-6, alpha tumor necrosis factor and depression status in bipolar patients

Protocol summary

Study aim

Determining the effect of omega-3 supplementation on serum interleukin 6 level, tumor necrosis factor alpha and depressive status in bipolar patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients.

Settings and conduct

The study will be conducted on 60 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

1) Means of interleukin 6 and tumor necrosis factor-alpha
2) Depression score in the Hamilton questionnaire

General information

Reason for update

Termination of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20211220053469N1**
Registration date: **2021-12-29, 1400/10/08**
Registration timing: **prospective**

Last update: **2022-04-17, 1401/01/28**
Update count: **2**

Registration date

2021-12-29, 1400/10/08

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

2022-01-27, 1400/11/07

Expected recruitment end date

2022-04-13, 1401/01/24

Actual recruitment start date

2022-01-09, 1400/10/19

Actual recruitment end date

2022-01-12, 1400/10/22

Trial completion date

2022-03-14, 1400/12/23

Scientific title

The assessment of the effect of omega-3 supplementation on serum interleukin-6, alpha tumor necrosis factor and depression status in bipolar patients

Public title

The assessment of the effect of omega-3 supplementation on serum interleukin-6, alpha tumor necrosis factor and depression status 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

- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

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

2021-12-25, 1400/10/04

Ethics committee reference number

IR.ZAUMS.REC.1400.319

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 interleukin 6

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 alpha tumor necrosis factor
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
Depression score on the Hamilton questionnaire
Timepoint
At the beginning of the study (before the intervention) and 60 days after the start of omega-3 supplementation
Method of measurement
Hamilton questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 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: 30 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
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9813913777
Phone
+98 54 3351 3777
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
Persian Gulf Boulevard., Dr. Hesabi Square., Campus of the University of Medical Sciences., Headquarters Building., Second Floor
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3337 2116
Email
zaums.research@gmail.com
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
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
Phone
+98 54 3348 4862
Email
hadi_eslahi2015@zaums.ac.ir

Person responsible for scientific 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
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
Phone
+98 54 3348 4862
Email
hadi_eslahi2015@zaums.ac.ir

Person responsible for updating data

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
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
Phone
+98 54 3348 4862
Email
hadi_eslahi2015@zaums.ac.ir

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