

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

An assessment on the effectiveness of Omega-3 as add-on therapy in mood stabilization in adolescents with bipolar disorder under treatment consuming lithium plus second-generation antipsychotic (aripiprazole or risperidone): a double-blind clinical trial.

Protocol summary

Study aim

An assessment on the effectiveness of Omega-3 as add-on therapy in mood stabilization in adolescents with bipolar disorder under treatment consuming lithium plus aripiprazole or lithium plus risperidone.

Design

A clinical trial study with a control group with double-blind and randomized parallel groups in phase 3 on 50 patients, randomly coding identical packages containing drugs in the same size and shape as Omega-3 and placebo

Settings and conduct

Outpatients in Roozbeh Hospital referring to the clinic and being hospitalized in the ward

Participants/Inclusion and exclusion criteria

Bipolar patients in the mixed phase and depression phase (admission conditions) No entry: Mentally retarded patients Patients with autism spectrum No drug use of any kind in the last month Suffering from physical and neurological diseases Contraindication to Omega-3 (heart problems)

Intervention groups

Drug-treated bipolar patients with inadequate response randomly treated with Omega-3 or placebo

Main outcome variables

The effectiveness of Omega-3 on the improvement of mood in bipolar patients under treatment

Last update: **2023-01-21, 1401/11/01**

Update count: **0**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

zeynab saadatfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 4829

Email address

zynbsadtfr4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An assessment on the effectiveness of Omega-3 as add-on therapy in mood stabilization in adolescents with bipolar disorder under treatment consuming lithium plus second-generation antipsychotic (aripiprazole or risperidone): a double-blind clinical trial.

Public title

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220418054579N1**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **retrospective**

An assessment on the effectiveness of Omega-3 as add-on therapy in mood stabilization in patients with bipolar disorder.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Bipolar patients in the mix phase plus depression phase

Exclusion criteria:

Mentally retarded patients Patients with autism spectrum

No drug use of any kind in the last month Suffering from physical and neurological diseases Contraindication to Omega-3 (heart problems)

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients referred to Rozbeh Hospital as outpatients or inpatients diagnosed with bipolar disorder who were treated with lithium and Aripiprazole or lithium and risperidone after being interviewed based on the Ksads questionnaire and completing other questionnaires by the project manager, referred to the clinic. And from the secretary of the clinic, they received the coded medicine, code 1 (omega 3) or code 2 (placebo) randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Omega-3 and placebo drugs are in the form of pills of the same shape and size in the same packages marked with codes 1 and 2 and given to the patients by the clinic secretary, so that the prescribing doctor and the patient and the patient's family are not aware of its content.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical

Sciences

Street address

No 3, floor 4, West Roein tan, street modarres, Sq gheibi, city Rey

City

Tehran

Province

Tehran

Postal code

1843753158

Approval date

2022-03-11, 1400/12/20

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1522

Health conditions studied

1

Description of health condition studied

BIPOLAR

ICD-10 code

F31.6

ICD-10 code description

Bipolar disorder, current episode mixed

Primary outcomes

1

Description

Treatment response score in the CGI questionnaire

Timepoint

60 day

Method of measurement

Questionnaire (CGI), Questionnaire (KSADS), Questionnaire (YMRS), Questionnaire (BDI), Questionnaire (Conner's) Based on the above questionnaires, the patient enters the study in the mixed phase without comorbidities such as psychosis, autism and mental retardation and is treated with Omega 3 or placebo. Then, the response to treatment is measured with the CGI questionnaire.

Secondary outcomes

1

Description

The improvement of mood status in bipolar patients

Timepoint

60 Day

Method of measurement

CGI Questionnaire

Intervention groups

1

Description

Intervention group: Bipolar patients with insufficient

treatment response (according to CGI questionnaire) who are treated with lithium and aripiprazole or lithium and risperidone for six weeks, after interviewing and filling out questionnaires, are randomly treated with 2000 mg of omega-3 daily for 8 weeks and then the questionnaires were taken from the patients again. Manufacturer: Dr. Zahrawi Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Control group: bipolar patients with treatment response, bipolar patients with insufficient treatment response (according to CGI questionnaire) who are treated with lithium and aripiprazole or lithium and risperidone for six weeks, after interview and filling out questionnaires, they are treated with drug Placebo was placed randomly for 8 weeks and then the questionnaires were taken from the patients again. Manufacturer: Dr. Zahrawi Pharmaceutical Company

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Zeinab Saadatfar

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Tehran University of Medical Sciences, South Kargar Sr., Tehran

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Email

hosp_roozbeh@tums.ac.ir

Web page address

<https://roozbehhospital.tums.ac.ir/public/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Lack of financial support

Street address

No 3, floor 4, West Rooin tan, street modarres, Sq gheibi, city Rey

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Phone

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Email

zynbsadtfr4@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Lack of financial support

Proportion provided by this source

1

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Saadatfar

Position

Assistant Professor of Child and Adolescent Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Name of organization / entity

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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

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

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Saadatfar

Position

Assistant Professor of Child and Adolescent Psychiatry

Latest degree

Specialist

Other areas of specialty/work