

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of omega-3 fatty acids on the components of metabolic syndrome in schizophrenic, bipolar and schizoaffective patients taking olanzapine plus sodium valproate or olanzapine plus lithium.

Protocol summary

Summary

The goal of this trial is to assess the efficacy of omega 3 fatty acids in preventing the development of the components of metabolic syndrome in psychiatric patients taking olanzapine. 50 adults aged 18 to 60 years taking combination of olanzapine and sodium valproate or olanzapine and lithium due to a psychiatric disorder (schizophrenia, bipolar mood disorder, schizoaffective disorder) will be included. Participants will be randomized according to the adjunctive treatment (lithium/ sodium valproate) and smoking status into 4 groups. In each group participants will be given omega 3 capsules or placebo capsules (double blind) for a total of 6 weeks. Each active drug capsule contains 1000 mg omega 3 fatty acids (300 mg EPA/DHA). Omega 3 or placebo capsules will be titrated as 1 capsule/day in the first intervention week, 2 capsules/day (divided) in the second intervention week and 3 capsules/day (divided) from the third intervention week till the end of intervention (end of week 6). Parameters measured would be: weight, height, waist circumference, blood pressure, fasting lipid profile, fasting blood sugar, fasting insulin, HgbA1c, Lp (a), CRP-hs at baseline and after the 6 week intervention. BMI and HOMA-IR would also be calculated accordingly at the same times mentioned

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712231764N1**
Registration date: **2009-05-26, 1388/03/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-05-26, 1388/03/05

Registrant information

Name

Toktam Faghihi

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

tfaghihi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical sciences

Expected recruitment start date

2008-06-21, 1387/04/01

Expected recruitment end date

2009-06-21, 1388/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega-3 fatty acids on the components of metabolic syndrome in schizophrenic, bipolar and schizoaffective patients taking olanzapine plus sodium valproate or olanzapine plus lithium.

Public title

omega 3 and metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: psychiatric patients taking olanzapine plus sodium valproate or olanzapine plus lithium with clinical diagnosis of schizophrenia, bipolar mood disorder, schizoaffective disorder, ages between 18-60 yrs. Exclusion criteria: 1- Previous treatment with study drugs (olanzapine, sodium valproate, lithium) during the three months prior to trial initiation/participation, 2- Having a significant active medical problem or abnormal lab tests before initiation of trial including: Liver function tests ≥ 3 normal, Thyroid stimulating hormone > 4.2 m.I.U/L, GFR < 60 ml/min, FBS > 125 mg/dl, TG ≥ 500 mg/dl, TG between 200-500 and Non-HDL cholesterol greater than or equal to 30+ target LDL: in cases of TG between 200-500, first Non-HDL cholesterol is calculated. Then the goal LDL of the patient is assessed according to NCEP ATP III LDL goals. Participants with TG between 200-500 are excluded if their Non-HDL cholesterol is greater than or equal to 30 + target LDL. 3- Pregnancy and lactation 4-Recent (within 4 weeks) consumption of omega 3 fatty acids 5-BMI ≥ 30 6-Contraindications for the study drugs 7-Patients or their family refusal to participation 8-Taking Drugs much affecting study parameters.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

Tehran

Postal code

Approval date

2008-11-12, 1387/08/22

Ethics committee reference number

7309

Health conditions studied

1

Description of health condition studied

schizophrenia, bipolar mood disorder, schizoaffective

ICD-10 code

F20, F25,

ICD-10 code description

Schizophrenia ,Schizoaffective disorders ,Bipolar affective disorder

Primary outcomes

1

Description

Weight

Timepoint

at the beginning of the study and 6 weeks after intervention.

Method of measurement

digital scale

2

Description

Height

Timepoint

at the beginning of the study.

Method of measurement

standard methods

3

Description

BMI

Timepoint

at the beginning of the study and 6 weeks after intervention.

Method of measurement

Calculated as body weight (kg) divided by the height in meters squared.

4

Description

Waist circumference

Timepoint

At the beginning of the study and 6 weeks after intervention.

Method of measurement

measuring tape

5

Description

Blood pressure

Timepoint

At the beginning of the study and 6 weeks after intervention.

Method of measurement

Mercury sphygmomanometer.

6

Description

FBS

Timepoint

At the beginning of the study and 6 weeks after intervention.

Method of measurement

Enzymatic procedure

7

Description

High-density lipoprotein (HDL)

Timepoint

At the beginning of the study and 6 weeks after intervention.

Method of measurement

Enzymatic procedure

8

Description

TG

Timepoint

At the beginning of the study and 6 weeks after intervention.

Method of measurement

Enzymatic procedure

Secondary outcomes

1

Description

Total cholesterol

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Enzymatic assays

2

Description

LDL

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Enzymatic assays (Directly measured)

3

Description

VLDL

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Calculated using the formula: TC (total cholesterol)- (HDL+ LDL)

4

Description

Non-HDL cholesterol

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Calculated by the formula: Total cholesterol- HDL-c

5

Description

Fasting Insulin

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Chemiluminescence

6

Description

Hgb A1C

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Immunoturbidimetry

7

Description

HOMA-IR

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Calculated

8

Description

Lipoprotein (a)

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Immunoturbidimetry

9

Description

Fibrinogen

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Clauss Coagulation method

10

Description

CRP-hs

Timepoint

At the beginning of the study and 6 weeks after intervention

Method of measurement

Immunoturbidimetry

Intervention groups

1

Description

Intervention: omega 3 capsules 1000 mg (containing 300 mg EPA/DHA). 1 capsule/day in the first intervention week, 2 capsules/day (divided) in the second intervention week and 3 capsules/day (divided) from the third intervention week till the end of intervention (end of week 6).

Category

Prevention

2

Description

Control: placebo, 1 capsule/day in the first intervention week, 2 capsules/day (divided) in the second intervention week and 3 capsules/day (divided) from the third intervention week till the end of intervention (end of week 6).

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Roostbeh Psychiatric Hospital

Full name of responsible person

Prof P Ghaeli

Street address

Roostbeh hospital, south Kargar street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr A Fotouhi

Street address

Tehran university of medical sciences, Keshavarz Blv

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. T. Faghihi

Position

Pharm. D., Clinical pharmacy resident

Other areas of specialty/work

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Pharm D, clinical pharmacy resident

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Postal code**Phone****Fax****Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. T. Faghihi

Position

Pharm.D., Clinical Pharmacy Resident

Other areas of specialty/work**Street address**