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
Roozbeh Psychiatric Hospital
Full name of responsible person
Prof P Ghaeli
Street address
Roozbeh 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
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, Enqelab st.
City
Tehran
Postal code
Phone
+98 21 6695 4709
Fax
Email
tfaghihi@razi.tums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, Enqelab st
City
Tehran
Postal code
Phone
+98 21 6695 4709
Fax
Email
tfaghihi@razi.tums.ac.ir
Web page address

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., Cinical Pharmacy Resident
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, Enqelab st
City
Tehran
Postal code
Phone
Fax
Email
tfaghihi@razi.tums.ac.ir
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