

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Assessment efficacy of omega-3 on metabolic and inflammatory Indices in patients with schizophrenia taking clozapine and sodium valproate in Mashhad, Iran

Protocol summary

Summary

The aim of the study: To determine the effect of adding omega3 on metabolic and inflammatory mediators in patients with schizophrenia treated with clozapine and valproate in Hejazi and Ibn e Sina hospital in Mashhad. Study design: Randomized, double-blind, placebo-controlled, single-center, phase II trial. Inclusion criteria: patients with schizophrenia admitted in Hejazi and Ibn Sina hospital in Mashhad that treated with clozapine and valproate at least 3 months (clozapine dose of 200 to 400 mg); Age 18 years or older; triglyceride levels in the morning between 200 to 499 Milligrams per deciliter; metabolic indices of patients before starting treatment with clozapine and valproate are normal. Exclusion criteria: Pregnancy or Lactation; history of sensitivity to fish oil; use of omega3 in the past few months; Having obvious bleeding disorders or a history of using heparin and coumarin; The reluctance of patients participating in the study; use of other drugs such as statins; history of consumption or abuse of alcohol or drugs within 6 months from baseline. Intervention: In the intervention group all patients who received clozapine daily 300 to 400 mg a day for 3 months receive omega3 (4 Grams per day) for 8 weeks. In the control group patients who received clozapine 300 to 400 mg a day for 3 months received placebo for 8 weeks. The primary outcome or consequences of the study: inflammatory mediators and metabolic changes. The primary outcome: Height, weight, waist circumference, body mass index, triglyceride levels, total cholesterol, LDL, HDL and CRP and inflammatory markers HSP, PAB, SOD, ZN, CU at the beginning and end of week 8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603095280N23**

Registration date: **2016-05-06, 1395/02/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-06, 1395/02/17

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina
Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Mashhad University of
Medical Sciences

Expected recruitment start date

2014-09-21, 1393/06/30

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment efficacy of omega-3 on metabolic and inflammatory Indices in patients with schizophrenia taking clozapine and sodium valproate in Mashhad, Iran

Public title

Effect of omega-3 on metabolic and inflammatory indices in patients with chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with schizophrenia admitted in Hejazi and Ibn Sina hospital in Mashhad that treated with clozapine and valproate at least 3 months (clozapine dose of 200 to 400 mg); Age 18 years or older; triglyceride levels in the morning between 200 to 499 Milligrams per deciliter; metabolic indices of patients before starting treatment with clozapine and valproate are normal. Exclusion criteria: Pregnancy or Lactation; history of sensitivity to fish oil; use of omega-3 in the past few months; Having obvious bleeding disorders or a history of using heparin and coumarin; The reluctance of patients participating in the study; use of other drugs such as statins; history of consumption or abuse of alcohol or drugs within 6 months from baseline.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical sciences

Street address

Qoreishi Building, Daneshgah St.

City

Mashhad

Postal code**Approval date**

2014-01-15, 1392/10/25

Ethics committee reference number

921429

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

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

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

height

Timepoint

baseline and week 8

Method of measurement

meter

2**Description**

Weight

Timepoint

baseline and week 8

Method of measurement

scale

3**Description**

abdominal circumference

Timepoint

baseline and week 8

Method of measurement

meter

4**Description**

BMI

Timepoint

baseline and week 8

Method of measurement

kg/m²

5**Description**

Triglyceride levels

Timepoint

baseline and week 8

Method of measurement

blood test

6**Description**

Cholesterol

Timepoint

baseline and week 8

Method of measurement

blood test

7**Description**

LDL

Timepoint

baseline and week 8

Method of measurement

blood test

8**Description**

HDL

Timepoint

baseline and week 8

Method of measurement

blood test

9**Description**

CRP

Timepoint

baseline and week 8

Method of measurement

blood test

10**Description**

Inflammatory Mediators

Timepoint

baseline and week 8

Method of measurement

blood test

11**Description**

CBC

Timepoint

baseline and week 8

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group all patients who received clozapine daily 300 to 400 mg a day for 3 months receive omega-3 (4 gr/day) for 8 weeks

Category

Treatment - Drugs

2**Description**

In the control group patients who received clozapine 300 to 400 mg a day for 3 months received placebo for 8 weeks .

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ibn E Sina Hospital

Full name of responsible person

Dr Narjes Roudbaraki

Street address

Ibn-e-Sina Hospita, Bu-Ali Sq., Amel Blvd., Mashhad, Iran

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mahyar Mirheydari

Street address

Qoreishi Building, Daneshgah St.

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Ibn e Sina Hospital

Full name of responsible person

Dr Narjes Roudbaraki

Position

Resident

Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Fatemeh Behdani

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associate professor

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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