Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of omega-3 on negative and positive symptoms in patients with chronic schizophrenia: a double blind and placebo controlled trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of omega-3 fatty acids would improve psychopathology in subjects with schizophrenia treated with typical antipsychotics. A total of 36 patients with chronic DSM-IV-diagnosed schizophrenia will receive chlorpromazine (1000 mg/day or equivalent dose of other typical antipsychotics) combined with either placebo or 3000 mg/day of omega-3 for 6 months. Efficacy will be defined as the change from baseline to endpoint in score on the Positive and Negative Syndrome Scale (PANSS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811022935N3**
Registration date: **2010-10-07, 1389/07/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-10-07, 1389/07/15

Registrant information

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Name of organization / entity
Kurdistan University of Medical Sciences
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farrezaei@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2010-08-14, 1389/05/23

Expected recruitment end date

2011-02-15, 1389/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 on negative and positive symptoms in patients with chronic schizophrenia: a double blind and placebo controlled trial

Public title

Omega-3 in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18 and 60, diagnosis of Schizophrenia based on DSM IV, chronic Schizophrenia
Exclusion Criteria: Substance dependence, any serious medical problem

Age

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

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **36**

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

Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd

City

Sanandaj

Postal code

Approval date

2007-03-19, 1385/12/28

Ethics committee reference number

10194

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Severity of schizophrenia

Timepoint

Baseline and 6 months after beginnig of treatmen

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description

Tablet chlorpromazine (1000mg/day) or equivalent doses of typical antipsychotics combined with 3000mg/day of omega-3 as intervention group for 6 months

Category

Treatment - Drugs

2

Description

Tablets chlorpromazine(1000 mg/day) or equivalent doses of typical antipsychotics combined with placebo as control group for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar institute

Full name of responsible person

Farzin Rezaei

Street address

Baharan district

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ataollah Heydari

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Deputy of research, Kurdistan university of Medical Sciences, Pasdaran Blvd., Sanandaj

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kurdistan 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

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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