

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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

Name

Farzin Rezaei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1356 1822

Email address

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
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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

Contact

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Person responsible for updating data

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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