

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Efficacy of Omega-3 in the treatment of Schizophrenia

Protocol summary

Summary

The goal of research is the study of the efficacy of Omega-3 in the treatment of schizophrenia. The method of research is randomized triple blind placebo controlled clinical trial. Study population are both inpatient and outpatient schizophrenics referred to Amirkabir hospital and Imamreza clinic. Inclusion criteria: age range 15-55 years, diagnosis of schizophrenia according to DSM4-TR criteria and clinical interview by psychiatrist, informed written consent letter, a score of at least 60 in PANSS(Positive and Negative Syndrome Scale). Exclusion criteria: Pregnancy ,lactation, substance abuse, severe physical disease, contraindication of Omega-3 60 patients are randomly divided in two groups(intervention and control). Each group receive an atypical antipsychotic for 8 weeks. In addition to antipsychotic, intervention group receive Omega3 1000mg/day, and controlled group receive placebo. The time of intervention is 8 weeks from the start date. Primary outcome is change in PANSS(Positive and Negative Syndrome Scale) scores.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202117373N2**
Registration date: **2012-03-16, 1390/12/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-16, 1390/12/26

Registrant information

Name

Hamidreza Jamilian

Name of organization / entity

Arak University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and education

Expected recruitment start date

2012-03-01, 1390/12/11

Expected recruitment end date

2012-08-30, 1391/06/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Omega-3 in the treatment of Schizophrenia

Public title

Efficacy of Omega-3 in the treatment of Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age range 15-55 years, diagnosis of schizophrenia according to DSM4-TR criteria and clinical interview by psychiatrist, informed written consent letter, a score of at least 60 in PANSS(Positive and Negative Syndrome Scale). Exclusion criteria: Pregnancy, lactation, substance abuse, severe physical disease, contraindication of Omega-3

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Basij Square

City

Arak

Postal code

3819691187

Approval date

2012-02-06, 1390/11/17

Ethics committee reference number

90-120-6

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

The Schizophrenic Disorders Are Characterized in general by fundamental and characteristic distortions of thinking and perception, and affects that are inappropriate or blunted.

Primary outcomes

1

Description

PANSS

Timepoint

Before Intervention,4th Week,8th Week

Method of measurement

Physical Exam And Clinical Intrview

Secondary outcomes

1

Description

Extra Pyramidal Side Effects

Timepoint

Before Intervention And Once Every 4 Weeks

Method of measurement

Physical Examination And Clinical Interview

Intervention groups

1

Description

Control group recieve an oral atypical antipsychotic in therapeutic dose plus plasebo for eight weeks.

Category

Treatment - Drugs

2

Description

Intervention group recieve an oral Atypical antipsychotic in therapeutic dose plus omega3 1000mg/day per oral for eight weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Hospital

Full name of responsible person

Dr HamidReza Jamilian

Street address

Amirkabir Hospital

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr Changizi Ashtiyani

Street address

Basij Square

City

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Grant name

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

Yes

Title of funding source
Arak 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
Arak Univesity Of Medical Sciences

Full name of responsible person
Dr HmidReza Jamilian

Position
Assistant Professor Psychiatry

Other areas of specialty/work

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Board Of Psychiatry

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Arak, University Of Medical Sciences

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Assistant Professor Psychiatry

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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