Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 15-55years, 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 recieve an atypical antipsychotic for 8 weeks.In addition to antipsychotic, intervention group recieve Omega3 1000mg/day, and cotrolled group recieve 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)
Phone
+98 86 1222 5758
Email address
jamilian.hr@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chanceller 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 15-55years ,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 ,sever 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
Arak
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
Street address
Amirkabir Hospital
City
Arak
Postal code
3819691187
Phone
+98 86 1272 4526
Fax
+98 86 1272 4526
Email
Jamilian.HR@Arakmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak of University of Medical Sciences
Full name of responsible person
Dr .Hamidreza Jamilian
Position
Board Of Psychiatry
Other areas of specialty/work
Street address
Amirkabir Hospital
City
Arak
Postal code
3819691187
Phone
+98 86 1313 5075
Fax
+98 86 1272 4526
Email
Jamilian.HR@Arakmu.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak, University Of Medical Sciences
Full name of responsible person
Dr HamidReza Jamilian
Position
Assistant Professor Psychiatry
Other areas of specialty/work
Street address
Amirkabir Hospital
City
Arak
Postal code
3819691187
Phone
+98 86 1272 4526
Fax
+98 86 1272 4526
Email
Jamilian.HR@Arakmu.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