Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of omega-3 supplementation on social, communication and behavior problems children with autism spectrum disorder

Protocol summary

Summary

Autism spectrum disorders(ASD) are neurological disorders with different causes. Its assumed that children with ASD have abnormal neural connection, synaptic function and neurotransmitter imbalance. One study in Iran showed that ASD prevalence in school children is 1.9%. Although the cause of Autism is unknown, But environmental, Genetics and metabolic factors can be involved. It looks like that Genetics have a underlying role in ASD development. Other involved factors include Immunological, prenatal, neurological-anatomical and biochemical-psychological factors. According to increasing prevalence of Autism and because there is not any study on Omega-3 supplementation in people with Autism, current study is performed to investigation of effects of Omega-3 supplementation in patients with Autism and determine the condition of behavioral indices.

General information

Acronym

The effect of Omega-3 on Autism spectrum disororders

IRCT registration information

IRCT registration number: **IRCT2015122625699N1**
Registration date: **2016-01-24, 1394/11/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-24, 1394/11/04

Registrant information

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Name of organization / entity
National Nutrition and Food Technology Research Institute

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Recruitment status
Recruitment complete

Funding source
National Nutrition and Food Technology Research Institute

Expected recruitment start date
2016-01-20, 1394/10/30

Expected recruitment end date
2016-05-20, 1395/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of omega-3 supplementation on social, communication and behavior problems children with autism spectrum disorder

Public title

The effect of Omega-3 on Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of Autism by psychologist; age between 5 to 15 years old; tend to cooperation; the severity of symptoms be moderate to severe. Exclusion criteria: history of Omega3 supplementation; histiory of allergies to fish; people with diabetes and blood disorders; altered drug use in study duration; digestive symptoms in response to supplement intake.

Age
From **3 years** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **58**
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
National Nutrition and Food Technology Research Institute
Street address
National Nutrition and Food Technology Research Institute
City
Tehran
Postal code
009821
Approval date
2014-09-23, 1393/07/01
Ethics committee reference number
054569

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorders
ICD-10 code
F84.0
ICD-10 code description

Primary outcomes

1

Description
Autism severity
Timepoint
Before intervention and 2 months after intervention
Method of measurement
GARZ Questionnaire

Secondary outcomes

1

Description
Social ineractions
Timepoint
Before and 2 months after intervention
Method of measurement
GARZ Questionnaire

2

Description
Communication
Timepoint
Before and 2 months after intervention
Method of measurement
GARZ Questionnaire

3

Description
Repeated behaviours
Timepoint
Before and 2 months after intervention
Method of measurement
GARZ Questionnaire

Intervention groups

1

Description
The case subjects receive 1 omega-3 capsula daily produced by Zahravi company, Iran.
Category
Treatment - Drugs

2

Description
The control subjects receive 1 placebo capsula daily produced by same company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Omide Ayandeh Autism center
Full name of responsible person
Street address

City
Rasht

2

Recruitment center
Name of recruitment center
Mansour school of exceptional children
Full name of responsible person
Street address
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Nutrition and Food Technology Research Institute
Full name of responsible person
Mrs. Mina Hoseini
Street address
Nutrition school, Shaheed Beheshti University, Arghavane Gharbi St. , Shahrake Gharb, Tehran, Iran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Nutrition and Food Technology Research Institute
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