

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 disorders

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

Name

Saeid Doaei

Name of organization / entity

National Nutrition and Food Technology Research

Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 6643 6744

Email address

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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; history 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 interactions

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

Contact

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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