

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Poly Unsaturated Fatty Acid as a combination treatment in children with Attention Deficit Hyperactivity Disorder

Protocol summary

Summary

Objective: Considering the current controversies regarding the efficacy of PUFA in the treatment of children with ADHD, the present study is designed to evaluate the impact of these nutrients in this disorder. Methods and materials: 40 children, 6-12 years old with ADHD were randomly assigned in 2 groups. The first one received methylphenidate plus PUFA (241 mg DHA, 33mg EPA and 180 mg omega6) and the second one received methylphenidate with placebo. The patients were evaluated at the baseline and on weeks: 2, 4, 6, 8 and 10 by ADHD-Rating Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138803122000N1**

Registration date: **2011-05-21, 1390/02/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-21, 1390/02/31

Registrant information

Name

Rozita Davari Ashtiani

Name of organization / entity

Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 1023

Email address

rodavari@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Behavioral Sciences Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2009-09-01, 1388/06/10

Expected recruitment end date

2010-03-30, 1389/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Poly Unsaturated Fatty Acid as a combination treatment in children with Attention Deficit Hyperactivity Disorder

Public title

Omega-3 in the treatment of Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- children with 6-12 years of age, 2- ADHD diagnosis based on DSM-IV-TR, 3- Score of at least 20 in ADHD-RS (parent form). Exclusion criteria: 1- Any major comorbid psychiatric disorder except ODD and LD based on K-SADS, 2- IQ below 70, 3- Use of any psychotropic drug or substance in at least 2 weeks before the study, 4- any major neurological disease, 5- use of PUFA included substances or nutrients more than once a week

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

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

Behavioral sciences Research Center, Shahid Beheshti University of Medical sciences

Street address

Imam Hossein Hospital, Shahid Madani Street

City

Tehran

Postal code

1617763141

Approval date

2009-10-25, 1388/08/03

Ethics committee reference number

6309

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

ADHD severity

Timepoint

every 2 weeks

Method of measurement

ADHD-Rating Scale

Secondary outcomes

1

Description

drug adverse effects

Timepoint

every 2 weeks

Method of measurement

adverse effects questionnaire of methylphenidate and PUFA

Intervention groups

1

Description

Intervention group: methylphenidate 0.3-1 mg/kg/day+ PUFA 430 mg/day, for 10 weeks, dose adjustment based on therapeutic response and side effects

Category

Treatment - Drugs

2

Description

Control group: Methylphenidate 0.3-1 mg/kg/day + placebo (produced by the same company which produced PUFA), for 10 weeks, dose adjustment based on therapeutic response and side effects

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Rozita Davari-Ashtiani

Street address

Shahid Madani Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behavioral Sciences Research Center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Zahiroddin

Street address

Imam Hossein hospital, Shahid Madani street

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Behavioral Sciences Research Center, Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Rozita Davari-Ashtiani
Position
associate professor
Other areas of specialty/work
Street address
Imam hossein hospital, Shahid Madani street
City
Tehran
Postal code
1617763141
Phone
+98 21 7755 1023
Fax
+98 21 7755 1023
Email
rodavari@sbmu.ac.ir , rodavari@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical sciences
Full name of responsible person
Rozita Davari-Ashtiani
Position
Associate professor

Other areas of specialty/work
Street address
Imam hossein Hospital, shahid Madani Street
City
Tehran
Postal code
1617763141
Phone
+98 21 7755 1023
Fax
+98 21 7755 1023
Email
rodavari@sbmu.ac.ir , rodavari2yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical sciences
Full name of responsible person
Rozita Davari-Ashtiani
Position
associate professor
Other areas of specialty/work
Street address
Imam Hossein hospital, shahid Madani Street
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Phone
+98 21 7755 1023
Fax
+98 21 7755 1023
Email
rodavari@sbmu.ac.ir , rodavari@yahoo.com
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