Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of omega-3 supplement as an adjunctive therapy in children with attention deficit hyperactivity disorder

Protocol summary

Summary

The aim of the present study is to evaluate the efficacy of Omega 3 on ADHD in children through a double-blind, randomized, controlled trial. 66 outpatients, including 6-12 years old who clearly meet the DSM-IV-TR diagnostic criteria for ADHD(based on duiagnosis of a child psychiatrist) will be randomly assigned to receive Omega 3 (EPA 180mg, DHA 120mg BID) and methylphenidate (5 to 30 mg per day) or Methylphenidate (5 to 30 mg per day) and placebo for 8 weeks. The primary outcome measure is the Coner's and Parent ADHD Rating Scale. Patients will be assessed by a child psychiatrist at baseline, 2,4 and 8 weeks after the medication started. Side effects were also rated by side effects questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060128182N2**
Registration date: **2017-01-23, 1395/11/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-23, 1395/11/04

Registrant information

Name
Soleiman Mohammadzadeh
Name of organization / entity
Kurdistan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 87 3323 2168
Email address
dr.mohammadzadeh86@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of omega-3 supplement as an adjunctive therapy in children with attention deficit hyperactivity disorder

Public title

omega-3 supplement in attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of ADHD based on DSMIV age between 6-12 Exclusion Criteria: receiving of omega3 suplement during past 6 months; presence of seizures; mental retardation; having any psychiatric disorders

Age

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

Gender

Both

Phase

2-3

Groups that have been masked
No information
Sample size
Target sample size: **66**
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
Kurdistan University of Medical Sciences
Street address
Kurdistan University of Medical Science, Pasdaran Street
City
Sanandaj
Postal code
Approval date
2016-01-13, 1394/10/23
Ethics committee reference number
MUK.REC.1394.265

Health conditions studied

1

Description of health condition studied
Adult ADHD (Attention-deficit hyperactivity disorder)
ICD-10 code
F90.9
ICD-10 code description
Hyperkinetic disorder, unspecified

Primary outcomes

1

Description
Improvement in Attention-deficit symptoms
Timepoint
Baseline, second, fourth and eighth weeks after intervention
Method of measurement
Conner's and ADHD Rating Scales

2

Description
Improvement in Impulsivity symptoms
Timepoint
Baseline, third and sixth weeks after intervention
Method of measurement
Conner's and ADHD Rating Scales–Self-Report

3

Description
Improvement in hyperactivity symptome
Timepoint
Baseline, third and sixth weeks after intervention
Method of measurement
Conner's and ADHD Rating Scales–Self-Report

Secondary outcomes

1

Description
severity of ADHD symptoms
Timepoint
Baseline, second, fourth and eighth weeks after intervention
Method of measurement
ADHD Rating Scales, CGI

2

Description
side effect
Timepoint
second, fourth and eighth weeks after intervention
Method of measurement
Side effects quesionnaire

Intervention groups

1

Description
One group of patients are randomly assigned to receive methylphenidate in the intervention group. Methylphenidate 10 mg is prescribed for the first week, a daily tablet (half tablet in morning at 8 o'clock and half tablet at 16 o'clock); in the second week, two tablets are daily prescribed (one in the morning at 8 o'clock, one at 16 o'clock); if the weight is above 30 pounds, 3 tablets will be daily prescribed in the second week (one and a half tablet each morning at 8 o'clock, one and a half tablet at 16 o'clock). Therapeutic dosage of omega3 is prescribed a tablet daily for the first week (one tablet in the morning at 8 o'clock) and 2 tablets are daily prescribed in the second week (one tablet in the morning at 8 o'clock, one tablet at 16 o'clock).
Category
Treatment - Drugs

2

Description
One group of patients are randomly assigned to receive methylphenidate in the control group. Methylphenidate 10 mg is prescribed for the first week, a daily tablet (half tablet in morning at 8 o'clock and half tablet at 16 o'clock); in the second week, two tablets are daily prescribed (one in the morning at 8 o'clock, one at 16 o'clock); if the weight is above 30 pounds, 3 tablets will be daily prescribed in the second week (one and a half tablet each morning at 8 o'clock, one and a half tablet at 16 o'clock). Therapeutic dosage of placebo is prescribed a tablet daily for the first week (one cap in the morning at 8 o'clock) and 2 cap are daily prescribed in the second week (one cap in the morning at 8 o'clock, one cap at 16 o'clock).

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Medical, Educational and Terapeutic Center of Besat Hospital

Full name of responsible person
Soleiman Mohammadzadeh

Street address
Medical, Educational and Terapeutic Center of Besat Hospital, Keshawarz Street

City
Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kurdistan University of Medical Sciences

Full name of responsible person
Farzin Rezaei

Street address
Kurdistan University of Medical Sciences, Pasdaran Street

City
Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kurdistan 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
Kurdistan University of Medical Sciences

Full name of responsible person
Soleiman Mohammadzadeh

Position
Child and Adolescent Psychiatry

Other areas of specialty/work

Street address
Kurdistan University of Medical Sciences, Pasdaran Street

City
Sanandaj

Postal code

Phone
00

Fax

Email
dr.mohammadzadeh86@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kurdistan University of Medical Sciences

Full name of responsible person
Soleiman Mohammadzadeh

Position
Child and Adolescent Psychiatry

Other areas of specialty/work

Street address
Kurdistan University of Medical Sciences, Pasdaran Street

City
Sanandaj

Postal code

Phone
00

Fax

Email
dr.mohammadzadeh86@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kurdistan University of Medical Sciences

Full name of responsible person
Soleiman Mohammadzadeh

Position

Other areas of specialty/work
Street address
City
Postal code
Phone
+98 918 873 3986
Fax
Email
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