

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 diagnosis 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 supplement 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 questionnaire

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