

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Investigating the effectiveness of methylphenidate and multi chain polyunsaturated fatty acids in treatment of symptoms of attention deficit hyperactivity disorder (ADHD) among 6 to 12 children suffered from ADHD

Protocol summary

Summary

(1) Objectives: Investigate the effect of methylphenidate drug combination plus several chain polyunsaturated fatty acids for the treatment of attention deficit hyperactivity disorder (ADHD) (2) Design: Randomized, Double blind, Placebo controlled, Single center, Phase 2 clinical trial (3) Setting and conduct: After selecting the patients and achieving their parent's consent, the method and the purpose of this study were explained to them. Then, a demographic information form was completed for each child separately. Patients were randomly divided into two groups using a table of random numbers (4) Participants including major eligibility criteria: Inclusion criteria: Aged 6 to 12 years; diagnosis of attention deficit hyperactivity disorder (ADHD) based on DSM-IV-TR diagnostic criteria Exclusion criteria: Any simultaneous major psychiatric disease, except confrontational behavior and learning disorder Target sample size: 40 (5) Intervention: In the intervention group: Methylphenidate tablets orally used with a starting dose of 0.3 mg/kg, twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and Omega-3 capsules that contain 180 mg docosahexaenoic acid (DHA) and 120 mg eicosapentaenoic acid (EPA), one per day for 8 weeks In the control group: Methylphenidate tablets were used orally with a starting dose of 0.3 mg/kg twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and received placebo capsules, once each day for 8 weeks (6) Main outcome measures (variables): Medication, Side effects, Disorder severity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092724209N2**

Registration date: **2016-04-28, 1395/02/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-28, 1395/02/09

Registrant information

Name

Mahboubeh Firoozkouhi Moghadam

Name of organization / entity

Zahedan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5796

Email address

m.firoozkoohi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology at Zahedan University of Medical Sciences and Health Services

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of methylphenidate and multi chain polyunsaturated fatty acids in treatment of symptoms of attention deficit hyperactivity disorder (ADHD) among 6 to 12 children suffered from ADHD

Public title

Investigating the effectiveness of methylphenidate and multi chain polyunsaturated fatty acids in treatment of patients with attention deficit hyperactivity disorder (ADHD) in Zahedan City

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged 6 to 12 years; diagnosis of attention deficit hyperactivity disorder (ADHD) based on DSM-IV-TR diagnostic criteria; the scale to measure attention deficit hyperactivity disorder (ADHD) in parent and teacher form, at least 20. Exclusion criteria: Any simultaneous major psychiatric disease, except confrontational behavior and learning disorder; IQ less than 70; the use of psychotropic drugs or narcotic materials in the past two weeks; any important neurological diseases; taking any drug affecting the nervous system, at least two weeks prior to the study.

Age

No age limit

Gender

Both

Phase

3

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

Ethics Committee of Zahedan University of Medical Sciences and Health Services

Street address

Pardis office complex at Zahedan University of Medical Sciences and Health Services, Persian Gulf Boulevard, Dr. Hessabi square, Zahedan, Iran

City

zahedan

Postal code

98167-43463

Approval date

2014-11-23, 1393/09/02

Ethics committee reference number

6752

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder (ADHD)

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Medication

Timepoint

Before intervention and 2, 4, 6 and 8 weeks after intervention

Method of measurement

Attention deficit hyperactivity disorder (ADHD) Rating Scale

Secondary outcomes

1

Description

Side effects

Timepoint

Before intervention and 2, 4, 6 and 8 weeks after intervention

Method of measurement

attention deficit hyperactivity disorder (ADHD) Rating Scale

2

Description

Disorder severity

Timepoint

Before intervention and 2, 4, 6 and 8 weeks after intervention

Method of measurement

attention deficit hyperactivity disorder (ADHD) Rating Scale

Intervention groups

1

Description

In the intervention group: Methylphenidate tablets orally used with a starting dose of 0.3 mg/kg, twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and Omega-3 capsules that contain 180 mg docosahexaenoic acid (DHA) and 120 mg eicosapentaenoic acid (EPA), one per day for 8 weeks

Category

Treatment - Drugs

2

Description

In the control group: Methylphenidate tablets were used orally with a starting dose of 0.3 mg/kg twice a day up to a final dose of 1 mg/kg within two weeks and continue treatment until 8 weeks after intervention and received placebo capsules, once each day for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharan Educational, Clinical and Research
Psychiatry Center

Full name of responsible person

Dr. Mahboubeh Firoozkouhi Moghadam

Street address

In front of the Grain office, Imam Khomeini street,
Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology at
Zahedan University of Medical Sciences and Health
Ser

Full name of responsible person

Dr. Houshang Rafighdoust

Street address

Pardis office complex at Zahedan University of
Medical Sciences and Health Services, Persian Gulf
Boulevard, Dr. Hessabi square, Zahedan, Iran

City

Zahedan

Grant name

125401

Grant code / Reference number

10506

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

Yes

Title of funding source

Vice Chancellor for Research and Technology at Zahedan
University of Medical Sciences and Health Ser

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

Vice Chancellor for Research and Technology at
Zahedan University of Medical Sciences and Health
Ser

Full name of responsible person

Dr. Houshang Rafighdoust

Position

Professor of Anatomy

Other areas of specialty/work

Street address

Pardis office complex at Zahedan University of
Medical Sciences and Health Services, Persian Gulf
Boulevard, Dr. Hessabi square, Zahedan, Iran

City

Zahedan

Postal code

98167-43463

Phone

+98 54 3329 5794

Fax

+98 54 3329 5796

Email

<http://highmail.zaums.ac.ir>

Web page address

www.zaums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Vice Chancellor for Research and Technology at
Zahedan University of Medical Sciences and Health
Ser

Full name of responsible person

Dr. Mahboubeh Firoozkouhi Moghadam

Position

University Assistant Professor

Other areas of specialty/work

Street address

Pardis office complex at Zahedan University of
Medical Sciences and Health Services, Persian Gulf
Boulevard, Dr. Hessabi square, Zahedan, Iran

City

Zahedan

Postal code

98167-43463

Phone

+98 54 3329 5794

Fax

+98 54 3341 6708

Email

m.firoozkoohi@zaums.ac.ir

Web page address

www.zaums.ac.ir

Medical Sciences and Health Services, Persian Gulf
Boulevard, Dr. Hessabi square, Zahedan, Iran

City

Zahedan

Postal code

98167-43463

Phone

+98 54 3329 5794

Fax

+98 54 3341 6708

Email

m.firoozkoohi@zaums.ac.ir

Web page address

www.zaums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Vice Chancellor for Research and Technology at
Zahedan University of Medical Sciences and Health
Ser

Full name of responsible person

Dr. Mahboubeh Firoozkouhi Moghadam

Position

University Assistant Professor

Other areas of specialty/work

Street address

Pardis office complex at Zahedan University of

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