

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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Email address

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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	Pardis office complex at Zahedan University of Medical Sciences and Health Services, Persian Gulf Boulevard, Dr. Hessabi square, Zahedan, Iran
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	City zahedan
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	Postal code 98167-43463
Purpose Treatment	Approval date 2014-11-23, 1393/09/02
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.	Ethics committee reference number 6752
Age No age limit	Health conditions studied
Gender Both	1
Phase 3	Description of health condition studied Attention deficit hyperactivity disorder (ADHD)
Groups that have been masked No information	ICD-10 code F90.0
Sample size Target sample size: 40	ICD-10 code description Disturbance of activity and attention
Randomization (investigator's opinion) Randomized	Primary outcomes
Randomization description	1
Blinding (investigator's opinion) Double blinded	Description Medication
Blinding description	Timepoint Before intervention and 2, 4, 6 and 8 weeks after intervention
Placebo Used	Method of measurement Attention deficit hyperactivity disorder (ADHD) Rating Scale
Assignment Parallel	Secondary outcomes
Other design features	1
Secondary Ids empty	Description Side effects
Ethics committees	Timepoint Before intervention and 2, 4, 6 and 8 weeks after intervention
1	Method of measurement attention deficit hyperactivity disorder (ADHD) Rating Scale
Ethics committee	2
Name of ethics committee Ethics Committee of Zahedan University of Medical Sciences and Health Services	Description Disorder severity
Street address	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
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Ser

Full name of responsible person

Dr. Houshang Rafighdoust

Position

Professor of Anatomy

Other areas of specialty/work

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University Assistant Professor

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Full name of responsible person

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Position

University Assistant Professor

Other areas of specialty/work

Street address

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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