

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of zinc and omega-3 supplements in children with attention-deficit hyperactivity disorder

Protocol summary

Summary

To determine the effect of supplemental zinc and omega-3 as adjuvant therapy on children with ADHD. The study is designed as a randomized clinical trial with a placebo group. Inclusion criteria: 1. Age: 6-15 years, 2. Newly diagnosed patient, 3. No history of taking any psychiatric drug, 4. No other psychiatric disorders, 5. There is no contraindication for the use of zinc and omega 3, 6. Diagnosis of ADHD is based on diagnostic criteria in DSM IV and diagnostic interview of psychiatrist. Exclusion criteria: 1. Parents or children withdrew the study because of any reason, 2. Child is suffering from acute physical illness, 3. Children can't use oral drugs, 4. Complications of drugs is so high that we have to stop them, 5. Alter treatment, 6. The drug is not used, 7. Any previous psychiatric disorders, 8. Mental retardation, 9. The patient can't use drugs. The total number of cases is 150 patients. The Patients will classify in three equal groups as A, B or C randomly. A group of children will receive placebo and Ritalin daily. B group will receive Zinc supplement and Ritalin daily. C group will receive omega-3 supplement and Ritalin daily. All children will treat for 8 weeks after treatment. 48 questions Conner's Rating Scals questionnaire of parents will complete at 2 weeks, 4 weeks and 8 weeks after starting treatment in the presence of the researcher. 48 questions Conner's Rating Scals questionnaire of teachers will complete after explanations by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104166201N1**

Registration date: **2011-05-13, 1390/02/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-05-13, 1390/02/23

Registrant information

Name

Hamid Sheykholeslami

Name of organization / entity

Arak University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Department of Education and Research of Arak University of Medical Sciences

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-02-20, 1390/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc and omega-3 supplements in children with attention-deficit hyperactivity disorder

Public title

Effect of zinc and omega-3 supplements as adjuvant therapy in children with attention-deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age: 6-15 years, 2. Newly diagnosed patient, 3. No history of taking any psychiatric drug, 4. No other psychiatric disorders, 5. There is no contraindication for the use of zinc and omega 3, 6. Diagnosis of ADHD is based on diagnostic criteria in DSM IV and diagnostic interview of psychiatrist. Exclusion criteria: 1. Parents or children withdrew the study because of any reason, 2. Child is suffering from acute physical illness, 3. Children can't use oral drugs, 4. Complications of drugs is so high that we have to stop them, 5. Alter treatment, 6. The drug is not used, 7. Any previous psychiatric disorders, 8. Mental retardation, 9. The patient can't use drugs.

Age

From **6 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

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

Arak University of Medical Sciences

Street address

Shahid shiroodi Ave. Alamolhoda st.

City

Arak

Postal code

3819693345

Approval date

2011-02-14, 1389/11/25

Ethics committee reference number

89-100-90

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Hyperkinetic disorders

Primary outcomes

1

Description

Scores in questionnaire

Timepoint

before treatment and then 2 weeks, 4 and 8 weeks after treatment

Method of measurement

48 questions Conner's Rating Scals questionnaire

Secondary outcomes

1

Description

Adverse reactions

Timepoint

2 weeks, 4 weeks and 8 weeks after treatment

Method of measurement

drug adverse reactions questionnaire

Intervention groups

1

Description

Children will receive omega-3 supplement and Ritalin in the third group. Dose of omega-3 supplement is based on the weight of the child as follows: children less than 25 kg ,100 mg of EPA children between 26 to 35 kg ,200 mg of EPA and children above 36 kg , 400 mg of EPA.

Category

Treatment - Drugs

2

Description

Children will receive placebo with Ritalin in the first group.

Category

Placebo

3

Description

Children will receive Zinc supplement 15mg daily and placebo in the second group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Amir Kabir hospital

Full name of responsible person

Dr. Fatemh Dorreh

Street address

Alamol-hoda st.

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Education and Research of Arak
University of Medical Sciences

Full name of responsible person

Dr. Saeed Changizi Ashtiani

Street address

Pardis educational complex, Basij square

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Department of Education and Research of Arak
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

Arak University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Dorreh

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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