

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of therapeutic effects of Omega-3 and methylphenidate(Ritalin) in treating patients with Attention Deficit Hyperactivity Disorder

#### Protocol summary

##### Summary

This study is designed to evaluating and comparing the therapeutic effects of two drugs Omega-3 and Methylphenidate (Ritalin) in treating patients with attention deficit hyperactivity disorder. This study is a Clinical trial study and is a Parallel method that is performed on 85 cases of children aged six to twelve screening in Yazd city. So that 29 people were treated with Methylphenidate (Ritalin), 28 people were treated with omega-3 and others 28 people were in the placebo group. Children with Score > 65 on both parents and teachers version of conners rating scale , IQ > 70 using Kaufman brief intelligence test and Informed consent were included while children with occurrence of unintended side effect, who had previous treatment of ADHD and also who had taken omega 3 supplenet during past 3 months and severe psychiatric disorders were excluded from study.The tool used in this study was Conners standardized questionnaire. The scores that obtained from these questionnaires were analyzed with using Chi-square test and Paired-T-test in the software environment PASW 18.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201304035393N3**  
Registration date: **2013-07-03, 1392/04/12**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-07-03, 1392/04/12

##### Registrant information

##### Name

Hamid Reza Soltani.G

##### Name of organization / entity

Yazd Islamic Azad University, Medical Society of Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1623 1817

##### Email address

hrsgmed@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Islamic Azad University branch Yazd

##### Expected recruitment start date

2009-06-21, 1388/03/31

##### Expected recruitment end date

2011-04-24, 1390/02/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of therapeutic effects of Omega-3 and methylphenidate(Ritalin) in treating patients with Attention Deficit Hyperactivity Disorder

##### Public title

Omega-3 effects on Patient with attention deficit hyperactivity disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

(Inclusion criteria: Children with Score > 65 on both

parents and teachers version of Conners rating scale; IQ > 70 using Kaufman brief intelligence test; Informed consent) (Exclusion Criteria: occurrence of unintended side effects; previous treatment of ADHD; omega 3 supplement consumption during past 3 months; severe psychiatric disorders )

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **85**

#### 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

Ethic committee of Ali ben Abitaleb medical school,

##### Street address

Ali Ben Abitaleb Medical school, Islamic Azad University branch Yazd, Yazd, Iran

##### City

Yazd

##### Postal code

#### Approval date

2010-07-03, 1389/04/12

#### Ethics committee reference number

44215

## Health conditions studied

### 1

#### Description of health condition studied

Attention deficit hyperactivity disorder

#### ICD-10 code

F90.0

#### ICD-10 code description

Disturbance of activity and attention

## Primary outcomes

### 1

#### Description

Connors standard test for ADHD patients

#### Timepoint

4 weeks

#### Method of measurement

Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

(Control: Methylphenidate(Ritalin), 0.3-1 mg/kg three times a day ) (Intervention: Therapeutic doses of Omega-3 (1 gr), 3 capsules divided in three days with Methylphenidate(Ritalin), 0.3-1 mg/kg three times a day)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohadaye Kargar Hospital

##### Full name of responsible person

Hoda Hekmat

##### Street address

##### City

Yazd

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University of Yazd

##### Full name of responsible person

Nasrollah Bashardoost

##### Street address

Ali ben Abitaleb medical school, Safaeiyeh

##### City

Yazd

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University of Yazd

#### 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**  
Yazd Branch, Islamic Azad university  
**Full name of responsible person**  
Hamid Reza Soltani  
**Position**  
General practitioner  
**Other areas of specialty/work**  
**Street address**  
Ali Ben Abitaleb Medical school, Safaeiyeh  
**City**  
Yazd  
**Postal code**  
**Phone**  
+98 35 1821 0540  
**Fax**  
**Email**  
hrsgmed@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Yazd Branch, Islamic Azad University  
**Full name of responsible person**  
Naser Dashti  
**Position**  
Assistant professor of Psychiatry  
**Other areas of specialty/work**  
**Street address**  
Shohadaye Kargar Hospital  
**City**

Yazd  
**Postal code**  
**Phone**  
+98 35 1811 2000  
**Fax**  
**Email**  
Dr\_naserdashti@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Yazd Branch, Islamic Azad University  
**Full name of responsible person**  
Hamid Reza Soltani  
**Position**  
General Practitioner  
**Other areas of specialty/work**  
**Street address**  
Ali Ben Abitaleb Medical school,  
**City**  
Yazd  
**Postal code**  
**Phone**  
+98 35 1821 0540  
**Fax**  
**Email**  
hrsgmed@yahoo.com  
**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*