

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Investigating the effect of Folic acid on reducing appetite caused by the use of methylphenidate in children with attention deficit hyperactivity disorder

#### Protocol summary

##### Summary

Aim of the study: Investigating the effect of Folic acid on reducing appetite caused by the use of methylphenidate in children with attention deficit hyperactivity disorder  
Key Inclusion Criteria: patients aged between 6 to 12 years old; ADHD diagnosing based on DSMIV; clinical need to treat with methylphenidate  
Key Exclusion Criteria: patients with epilepsy and diabetes; cardiovascular disorder; history of severe side effect with the previous use of methylphenidate  
Study Population: Seventy patients aged between 6 to 12 years old suffered from ADHD under treatment with methylphenidate. Random division: 35 patients in intervention group, 35 patients in control group.  
Study Intervention: in interventional group: receiving Folic acid (5mg/day) with of methylphenidate (average 1 mg/kg) for 8 weeks, in control group: receiving methylphenidate (average 1 mg/kg) with placebo for 8 weeks  
Primary outcome: Evaluation of appetite at the beginning of the study, after 2, 4 and 8 weeks with questionnaire and examination of height and weight

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040927304N1**  
Registration date: **2016-04-21, 1395/02/02**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-21, 1395/02/02

##### Registrant information

Name

Ghazal Salehi vanani

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3554 1578

##### Email address

salehivanani.gh@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Jundishapur University of Medical Sciences

##### Expected recruitment start date

2015-10-22, 1394/07/30

##### Expected recruitment end date

2016-06-20, 1395/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of Folic acid on reducing appetite caused by the use of methylphenidate in children with attention deficit hyperactivity disorder

##### Public title

Effect of Folic acid on reducing appetite caused by the use of methylphenidate in children with attention deficit hyperactivity disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients aged between 6 to 12 years old; ADHD diagnosing based on DSMIV; clinical need to

treat with methylphenidate; not receiving other pharmacological intervention 2 weeks before the intervention; completing consent form; ability to refer for follow up visits Exclusion criteria: patients with epilepsy and diabetes; cardiovascular disorder; disorder or using drugs that elevate sympathetic system activity like Pheochromocytoma; using Pseudoephedrine; psychosis in patient or in their parents; bipolar disorder; using any drugs and supplements which affect weight; low birth weight; history of prematurity; comorbid tourette, celiac, phenylketonuria, autism, mental retardation syndrome; failure to thrive approved in advance by pediatricians; history of severe side effect with the previous use of methylphenidate; mother drug user ;reduced appetite before the study; minor thalassemia

**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: **70**

**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**

Ahvaz Jundishapur University of Medical Sciences

**Street address**

Vice Chancellor for Research and Technology  
Development, universal city, Ahvaz

**City**

Ahvaz

**Postal code**

6135715794

**Approval date**

2015-10-17, 1394/07/25

**Ethics committee reference number**

IR.AJMS.REC.1394.416

**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**

Appetite score

**Timepoint**

0-2-4-6-8 weeks

**Method of measurement**

questionnaire

**Secondary outcomes****1****Description**

The weight change

**Timepoint**

0-2-4-6-8 weeks

**Method of measurement**

examination of weight

**2****Description**

The BMI change

**Timepoint**

0-2-4-6-8 weeks

**Method of measurement**

examination of weight and height and standard formula

**Intervention groups****1****Description**

Interventional group: receiving Folic acid (5mg/day) with of methylphenidate (average1 mg/kg) for 8 weeks

**Category**

Treatment - Drugs

**2****Description**

Control group: receiving methylphenidate (average1 mg/kg) with placebo for 8 weeks

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Child and Adolescents Psychiatric Clinic, Golestan Hospital

**Full name of responsible person****Street address**

Golestan hospital, Ahvaz, Khuzestan

**City**

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr. Nader Saki

**Street address**

Vice Chancellor for Research and Technology Development, universal city, Ahvaz

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz Jundishapur 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**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr.Ghazal Salehi Vanani

**Position**

Psychiatric resident

**Other areas of specialty/work****Street address**

Number 89, Pourmoghadam street, Padadshahr, Ahvaz

**City**

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**Postal code****Phone**

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Salehivanani.gh@ajums.ac.ir; dr.gh.salehi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr.Forugh Riahi

**Position**

Assistant Professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Dr.Ghazal Salehi Vanani

**Position**

psychiatric resident

**Other areas of specialty/work****Street address**

Number 89, Pourmoghadam street, Padadshahr, Ahvaz

**City**

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dr.gh.salehi@gmail.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*