Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 interventiol group: receiving Folic acid (5mg/day) with of methylphenidate (average1 mg/kg) for 8 weeks, in control group: receiving methylphenidate (average1 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

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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 sympathic 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
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Person responsible for updating data

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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