

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of short-term co-administration of folate on aggressive behaviors in Attention Deficit Hyperactivity Disorder (ADHD): a double blind randomized controlled trial

#### Protocol summary

##### Summary

This randomized controlled clinical trial investigates the efficacy of folic acid as an adjuvant medication on aggressive behaviors in children and adolescents with Attention Deficit Hyperactivity Disorder (ADHD). Children with ADHD and aggressive behaviors are included. Parents report their children aggressive behaviors using the ADHD Rating Scale and Over Aggressive Behavior Scale. Serious medical condition and lack of providing written informed consent are exclusion criteria. Forty qualified patients will be divided into intervention and control group randomly. Intervention group receive folic acid (5mg/day) and control group receive placebo. The participants are assessed every 30 days for 2 months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201108193930N11**  
Registration date: **2011-09-18, 1390/06/27**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-09-18, 1390/06/27

##### Registrant information

##### Name

Ahmad Ghanizadeh

##### Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1627 3070

##### Email address

ghanizad@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2011-08-19, 1390/05/28

##### Expected recruitment end date

2012-08-19, 1391/05/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of short-term co-administration of folate on aggressive behaviors in Attention Deficit Hyperactivity Disorder (ADHD): a double blind randomized controlled trial

##### Public title

The effect of short-term co-administration of folate on aggressive behaviors in Attention Deficit Hyperactivity Disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) according to DSM-IV diagnostic criteria; children and adolescents aged 7 to 19 years old. Exclusion criteria: Self reported an allergic reaction to folic acid; kidney disease; being on dialysis; infection; anemia; epilepsy; taking medications such as phenytoin, methotrexate, nitrofurantoin, tetracycline

barbiturates such as Phenobarbital, primidone; lack of providing written informed consent for participation; a diagnosed psychotic disorder; extensive use of nutritional folic acid supplements within the previous 3 months; behavior therapy or any other psychotherapy in the last three months or during this study.

#### **Age**

From **7 years** old to **19 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **40**

#### **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**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

##### **City**

Shiraz

##### **Postal code**

##### **Approval date**

2011-07-12, 1390/04/21

##### **Ethics committee reference number**

CT-90-2711

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Attention Deficit Hyperactivity Disorder (ADHD)

#### **ICD-10 code**

F 90

#### **ICD-10 code description**

Hyperkinetic disorders

## **Primary outcomes**

### 1

#### **Description**

ADHD rating questionnaire

#### **Timepoint**

every 30 days

#### **Method of measurement**

parent report

## **Secondary outcomes**

### 1

#### **Description**

modified Overt Aggression Scale

#### **Timepoint**

every 30 days

#### **Method of measurement**

parent report

## **Intervention groups**

### 1

#### **Description**

folic acid (5mg/day)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Placebo

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

##### **Full name of responsible person**

Ahmad Ghanizadeh

##### **Street address**

Hafez Hospital, Chamran Street

##### **City**

Shiraz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

Gholam Reza Hatam

**Street address**

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

**City**

Shiraz

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

Yes

**Title of funding source**

Vice chancellor for research, Shiraz 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Position**

MD

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

Hafez Hospital, Chamran Street

**City**

Shiraz

**Postal code****Phone**

+98 71 1627 3070

**Fax****Email**

ghanizad@sina.tums.ac.ir

**Web page address****Person responsible for updating data****Contact****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*