

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Evaluating and comparison of Cyproheptadine and Folic acid effects on appetite and hyperactivity and attention deficiency in children with ADHD receiving Ritalin

#### Protocol summary

##### Summary

The objective of this study is evaluating and comparison of Cyproheptadine and Folic acid effects on appetite and hyperactivity and attention deficiency in children with ADHD receiving Ritalin. forty children referring to private psychology clinic at the age range of 7-12 who meet the inclusion criteria will divide in to two groups in a double blind permuted block randomized allocation design based on gender blocks. One group taking Cyproheptadine (12mg 4mg before each meal) combined with Ritalin (1mg/kg), and the other group taking Folic acid (5mg/day) combined with Ritalin (1mg/kg). In the first visit, personal and demographic questionnaires, special tests for ADHD (based on diagnostic criteria for DSM-IV) such as ADHD Rating Scale, appetite questionnaire, and SDSC (Sleep Disturbance Scale for Children) sleep questionnaire will complete by mothers; and then, anthropometric measurements in standard situation will perform. ADHD rating scale, appetite questionnaire and SDSC sleep questionnaires will be completed by mothers at baseline, and will repeat at 2, 4, and 8 weeks after the treatment. Anthropometric assessments will done at baseline and will repeat 8 weeks after the treatment. At the end of study, the stimulant drug side effects questionnaire will complete by mothers; then, the side effects will compare between the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203167462N5**  
Registration date: **2012-04-22, 1391/02/03**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-04-22, 1391/02/03

##### Registrant information

###### Name

Mohammad Reza Mohammadi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5541 3540

###### Email address

pprc@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2012-04-18, 1391/01/30

##### Expected recruitment end date

2012-07-05, 1391/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating and comparison of Cyproheptadine and Folic acid effects on appetite and hyperactivity and attention deficiency in children with ADHD receiving Ritalin

##### Public title

Evaluating effects of Cyproheptadine and Folic acid in children with ADHD receiving Ritalin

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Age range of 7-12; ADHD combined form; Clinical need to treat with Methylphenidate; parental consent and child ascent Exclusion criteria: any confounding co-morbidity; any drug supplements or narcotics consumption; Children with history of major prenatal complications such as prematurity, low birth weight (reported by parents), any past or present psychosis, comorbid tourette syndrome, celiac, phenylketonuria, autism, or other persistent developmental disorders

## Age

From **7 years** old to **12 years** old

## Gender

Both

## Phase

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)

Triple blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Research Deputy of Tehran University of Medical Sciences, Keshavarz Avenue, Tehran. Iran

##### City

Tehran

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

31807

## 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

Attention deficiency score and Hyperactivity score

#### Timepoint

0-2-4-8 weeks

#### Method of measurement

ADHD rating scale for children (completed by parents)

### 2

#### Description

Appetite score

#### Timepoint

0-2-4-8 weeks

#### Method of measurement

Standard appetite questionnaire for children

### 3

#### Description

Sleep disorders score

#### Timepoint

0-2-4-8 weeks

#### Method of measurement

Sleep disorders scale for children (SDSC)

## Secondary outcomes

### 1

#### Description

Stimulants side effects

#### Timepoint

week 8

#### Method of measurement

Stimulants side effects questionnaire

## Intervention groups

### 1

#### Description

Intervention group1: Methyl phenidate (Ritlin: 1mg/kg) combined with Cyproheptadin (Razi: 12 mg/day- 4mg before each meal)

#### Category

Treatment - Drugs

2

**Description**

Intervention group2: Methyl phenidate (Ritlin: 1mg/kg) combined with Folic acid (Alhavi: 5 mg/day)

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Private clinic

**Full name of responsible person**

Dr. Mohammad Reza Mohammadi

**Street address**

Dr. Mohammad Reza Mohammadi private clinic, Zafar street, Vali-Asr street, Tehran. Iran

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Ahadi

**Street address**

Rasearch Deputy of Tehran University of Medical Sciences, Keshavarz Avenue, Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Mostafavi

**Position**

B.S.

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## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*