

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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-morbiditis; 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 (complited 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

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B.S.

Other areas of specialty/work

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>