

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the Efficacy of two brands of Methylphenidate (Stimdate® with Ritalin®) in Children and Adolescents with Attention Deficit Hyperactivity Disorder: A Double-Blind, Randomized, Clinical Trial

#### Protocol summary

##### Summary

The aim of this double blind trial was to compare the efficacy of Stimdate (methylphenidate-MPH produced in Iran) with Ritalin (methylphenidate's original brand) in children with ADHD. A total of thirty, 6-16 year-old children, who met inclusion and exclusion criteria; were studied in a comparative, double blind, randomized, clinical trial, in child psychiatric clinic of Tehran Psychiatric Institute, during 2008. The participants were randomly enrolled in the two groups to receive 10-40mg (in two divided daily doses) of two brands of MPH (Ritalin or Stimdate) for 6 weeks (4 weeks of fixed, 5-20mg MPH per dose) and 2 weeks of optimal dose (the best fixed-dose week). Side effects profile, Parent's Conner's Rating Scale (PCRS), Child Symptom Inventory-4-(CSI-4), Clinical Global Impressions (CGI), and Children's Global Assessment Scale (CGAS) were compared between groups at the baseline, and at the end of the 4th and the 6th week.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201106306923N1**

Registration date: **2011-11-04, 1390/08/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-11-04, 1390/08/13

##### Registrant information

##### Name

Elham Shirazi

**Name of organization / entity**

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2209 5680

##### Email address

eshirazi@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2008-04-20, 1387/02/01

##### Expected recruitment end date

2008-12-21, 1387/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Efficacy of two brands of Methylphenidate (Stimdate® with Ritalin®) in Children and Adolescents with Attention Deficit Hyperactivity Disorder: A Double-Blind, Randomized, Clinical Trial

##### Public title

The Efficacy of Stimdate and Ritalin in Children with ADHD: A Comparative, Double-Blind, Randomized, Clinical Trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age 6-16 years old; Presence of mixed AD/HD according to Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV), No

psychological medication in 2 weeks prior to the study; signing informed written consent of parents to participate in the study; the ability to comply study visits schedule. Exclusion criteria: Presence of clinically significant gastrointestinal problems, cardiovascular disease, glaucoma, seizure disorder, psychotic disorder, clinical depression, or Tourette's syndrome; Co-morbid conditions including oppositional defiant disorder or conduct disorder, pervasive developmental disorder, depression, or learning disorders

#### **Age**

From **6 years** old to **16 years** old

#### **Gender**

Both

#### **Phase**

N/A

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

*No information*

#### **Sample size**

Target sample size: **30**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

###### **Street address**

faculty of medicine, Iran University of Medical Sciences, Hemmat Exp.

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2009-06-23, 1388/04/02

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

11180

### **Health conditions studied**

#### **1**

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

ADHD

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

F90

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

A group of disorders characterized by an early onset (usually in the first five years of life), lack of persistence in activities that require cognitive involvement, and a tendency to move from one activity to another without completing any one, together

### **Primary outcomes**

#### **1**

##### **Description**

Clinical Profile of illness reported by parents

##### **Timepoint**

4th and 6th week

##### **Method of measurement**

The Standard Persian version of Conner's parent rating scale-revised (CRS-R) was used for the assessment of ADHD in children and adolescents.

#### **2**

##### **Description**

efficacy of treatment

##### **Timepoint**

4th and 6th week

##### **Method of measurement**

The Clinical Global Impressions (CGI) Scale used to rate the symptoms change over time, and efficacy of medication, taking into account the patient's clinical condition by clinicians.

#### **3**

##### **Description**

symptoms severity reported by parents

##### **Timepoint**

0,4,6 weeks

##### **Method of measurement**

The Child Symptom Inventory-4 (CSI-4) (ADHD part): is also used to measure Symptom Severity scores by teachers and parents<sup>24-25</sup>. The internal consistency reliability for CSI-4 in literature reported to be 0.74-0.94 and have acceptable criterion validity.

#### **4**

##### **Description**

illness severity

##### **Timepoint**

4th and 6th week

##### **Method of measurement**

The Children's Global Assessment Scale (CGAS) is used to measure the overall severity of disturbance in children. The CGI and CGAS showed acceptable reliability and validity scores in different studies.

### **Secondary outcomes**

## 1

### Description

Drug side effects

### Timepoint

4th and 6th week

### Method of measurement

checklist by clinical interview and exam

## Intervention groups

## 1

### Description

Intervention Group: In this group 15 subjects with ADHD were treated with Stimdate® as follow: Starting with 5 mg at morning and noon and weekly increments by 5mg in each dose to reach the dose of 20mg at morning and noon in the 4th week. The dose of the 5th and 6th week was determined according to best response to doses.

### Category

Treatment - Drugs

## 2

### Description

The control group contained 15 subjects who were treated with Ritalin® as follow: Starting with 5 mg at morning and noon and weekly increments by 5mg in each dose to reach the dose of 20mg at morning and noon in week four. The dose of Ritalin in the 5th and 6th week was determined according to best response to doses.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Tehran Psychiatry Institute

#### Full name of responsible person

#### Street address

#1, Shahid Mansouri St., Niayesh St., Sattarkhan Ave.

#### City

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Mehrdad Eftekhari Ardebili

#### Street address

Mental Health Research Center, Tehran Psychiatric Institute, Shahid Mansouri St., Niayesh St., Sattarkhan Ave., Tehran, 1443813444, Iran

#### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Mental Health Research Center

#### Full name of responsible person

Elham Shirazi

#### Position

Associate professor

#### Other areas of specialty/work

#### Street address

No.1, Shahid Mansouri St., Niayesh St., Sattarkhan Ave.

#### City

Tehran

#### Postal code

1443813444

#### Phone

+98 21 6650 6862

#### Fax

+98 21 6650 6862

#### Email

shirazi\_elham@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mental Health Research Center

#### Full name of responsible person

Elham Shirazi

#### Position

Associate Professor

#### Other areas of specialty/work

#### Street address

No1. Shahid Mansouri St., Niayesh St., Sattarkhan Ave.

#### City

Tehran

**Postal code**

1443813444

**Phone**

+98 21 6650 6862

**Fax**

+98 21 6650 6862

**Email**

shirazi\_elham@yahoo.com

**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*