Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran University of Medical Siences
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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 parents24-25. 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 Eftekhar Ardebili
Street address
Mental Health Research Center, Tehran Psychiatric Institute, Shahid Mansouri St., Niayesh St., Sattarkhan Ave., Tehran, 1443813444, Iran
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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
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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