

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of Ritalin, Stimdate and Practisa in primary school children with Attention Deficit Hyperactivity Disorder

Protocol summary

Study aim

Determining the effectiveness of Ritalin, Stimedid and Practisesa drugs in primary school children with attention deficit hyperactivity disorder

Design

Clinical trial, Double-blind, Randomized phase 2 on 60 patients, Block allocation method will be used for randomization.

Settings and conduct

The study will be conducted on children suffering from attention-deficit hyperactivity disorder referred to the Ba'ath Hospital clinic in Sanandaj.

Participants/Inclusion and exclusion criteria

Entry Criteria: 1. The age of these children should be 6 to 12 years. 2. Based on the diagnostic criteria of DSM-5, a child and adolescent psychiatry specialist should diagnose attention deficit hyperactivity disorder in children. Study exclusion criteria: 1. Existence of serious physical disease such as seizure disease, heart disease based on parents' history and clinical suspicion 2. Presence of accompanying psychiatric disorder 3. Mental retardation based on clinical suspicion 4. Taking drugs for attention deficit hyperactivity disorder in the last month

Intervention groups

Intervention group: The patients included in the study are divided into three groups during a period of 8 weeks. Each group is given one of the drugs Ritalin, Methylphenidate Iranian Stimulant or Practice. The patient will be visited at the beginning of the study (baseline), 2 weeks, 4 weeks, and 8 weeks later, and they will be checked for complications and reduction of symptoms, and the ADHD Rating Scale and CGI questionnaire will be completed.

Main outcome variables

The person's score is based on Parent's ADHD Rating scale and CGI (Clinical Global Impressions) questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160530028182N10**

Registration date: **2023-09-20, 1402/06/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-20, 1402/06/29**

Update count: **0**

Registration date

2023-09-20, 1402/06/29

Registrant information

Name

Soleiman Mohammadzadeh

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Ritalin, Stimdate and Practisa in primary school children with Attention Deficit Hyperactivity Disorder

Public title

Effectiveness of Ritalin, Stimedite and Practisa in primary school children with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The age of these children is 6 to 12. Based on the diagnostic criteria of DSM-5, the child and adolescent psychiatry specialist should diagnose attention deficit hyperactivity disorder in children.

Exclusion criteria:

Existence of serious physical disease such as seizure disease, heart disease based on parents' history and clinical suspicion Presence of accompanying psychiatric disorder Mental retardation based on clinical suspicion Taking drugs for attention deficit hyperactivity disorder in the last month

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block allocation method will be used for random allocation in this study. In this way, according to age, patients are categorized into two age groups: 6-8 years old and 9-11 years old. Then the patients have criteria for entering the study based on whether they are in the group of 6-8 years old or the group of 9-11 years old and based on coincidence, the first person aged 6-8 years old is in one of the treatment groups and the second and third person aged 6-8 years old respectively in The second and third groups of treatment are placed, and also based on the coincidence, the first person aged 9-11 is placed in one of the treatment groups, and the second and third person, 9-11 years old, are placed in the second and third treatment groups, respectively, and this process continues until completion. The sample size will continue. How to group, allocate and blind: In order for the study to be double-blind, the researcher randomly divides the subjects into groups 1, 2, and 3, and they are referred to the person responsible for the treatment (pharmacy) with such a code. Ritalin, Stimedite and Practisa are placed in the same capsules and are given to patients by the pharmacy in pre-prepared envelopes

according to codes 1, 2 and 3. The therapeutic dose of methylphenidate tablets 10 mg manufactured by Novartis company for the first week (daily, one quarter in the morning and one quarter in the evening), the second week (daily, one half in the morning and one half in the evening) and the third week onwards based on the patient's tolerance (daily, one in the morning and one in the evening) is recommended. It should be noted that it will be done in the same way in each age group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient does not know in which treatment group he has been placed, the patient's family also does not know in which treatment group he has been studied due to the fact that their patient receives standard treatment, and also the measurement subjects. The clinical outcome provider does not know how to categorize and how to group the studied subjects. Medicines are prepared and provided in coded packages that only the pharmacist is in the process of coding.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kurdistan University of Medical Sciences

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No. 1, Pasdaran Blvd. Sanandaj Town

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2022-11-08, 1401/08/17

Ethics committee reference number

IR.MUK.REC.1401.295

Health conditions studied**1****Description of health condition studied**

Attention-Deficit Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly

inattentive type

Primary outcomes

1

Description

Clinical Global Impressions Number

Timepoint

The beginning of the study (basic), 2 weeks, 4 weeks and 8 weeks after the study

Method of measurement

Clinical Global Impressions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients included in the study during a period of 8 weeks are divided into three groups. The first group is Iranian methylphenidate (stimulant) 10 mg manufactured by Mehr Daru company for the first week (daily, one quarter in the morning and one quarter in the evening), the second week (daily, one half in the morning and one half in the evening) and the third week onwards based on the patient's tolerance (daily, one in the morning and one in the evening) is prescribed. The patient will be visited at the beginning of the study (baseline), 2 weeks, 4 weeks, and 8 weeks later, and they will be checked for complications and reduction of symptoms, and the ADHD Rating Scale and CGI questionnaire will be completed.

Category

Treatment - Drugs

2

Description

Intervention group: The patients included in the study during a period of 8 weeks are divided into three groups. The second group is Iranian methylphenidate (Practisa) 10 mg manufactured by Vana Daru Gostar company for the first week (daily, one quarter in the morning and one quarter in the evening), the second week (daily, one half in the morning and one half in the evening) and the third week onwards based on the patient's tolerance (daily, one in the morning and one in the evening) is prescribed. The patient will be visited at the beginning of the study (baseline), 2 weeks, 4 weeks, and 8 weeks later, and they will be checked for complications and reduction of symptoms, and the ADHD Rating Scale and CGI questionnaire will be completed.

Category

Treatment - Drugs

3

Description

Intervention group: The patients included in the study during a period of 8 weeks are divided into three groups. The third group is Ritalin 10 mg manufactured by Novartis for the first week (daily, a quarter in the morning and a quarter in the evening), the second week (daily, a quarter in the morning and a quarter in the evening). one second in the evening) and the third week onwards based on the patient's tolerance (daily, one in the morning and one in the evening) is prescribed. It will be given. The patient will be visited at the beginning of the study (baseline), 2 weeks, 4 weeks, and 8 weeks later, and they will be checked for complications and reduction of symptoms, and the ADHD Rating Scale and CGI questionnaire will be completed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital Sanandaj

Full name of responsible person

Soliman Mohammadzadeh

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No. 1, Keshavarz St., South Mardukh St., Sanandaj Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Malaki

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Soliman Mohammadzadeh
Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Individual data of participants

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

People working in academic institutions
Under which criteria data/document could be used
Researchers in this field
From where data/document is obtainable
dr.mohammadzadeh86@muk.ac.ir

What processes are involved for a request to access data/document
2 Month
Comments