Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Survey on short-acting methylphenidate (Ritalin) vs. long-acting methylphenidate (Matoride) effectiveness on Attention deficit Hyperactivity Disorder symptom among 6 - 18 year-old children

Protocol summary

Study aim

Comparison of short-acting methylphenidate (Ritalin) vs. long-acting methylphenidate (Matoride) effectiveness on Attention deficit Hyperactivity Disorder symptom among 6 - 18 year-old children

Design

Clinical trial with parallel control group, double blinded and randomization.

Settings and conduct

This is a double-blind clinical trial in which the patient and distributor of the drug will not be aware of the type of medication. The sample size was 75 in each group (Ritalin and Methoroid). Ritalin is given at a dose of 10 mg and metribuide is given at a dose of 18 mg in the morning before going to school, and the child's performance after school hours is assessed by Parents' Conners Questionnaire. In this case, the short acting efficacy of Ritalin is not problematic, and both drugs can be evaluated in their half-life. Also, about the side effects of the drug, at the end of three weeks of treatment, the parents will be asked to complete the questionnaire after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Satisfaction with entering the study by the parent or patient 2. Having a minimum age of 6 and a maximum of 18 years of age 3. Confirm Diagnosis of Hyperactivity Disorder - DSM-5 Hyperactivity by Pediatric Psychiatrist 4. Lack of major psychiatric disorder Exclusion criteria: 1. Lack of patient and family cooperation to complete the intervention period 2. Receive other medications except matoride and ritalin 3. Having a physical illness that prevents the use of the drug

Intervention groups

For Intervention group 1, will be given a short-acting methylphenidate drug (Ritalin) manufactured by NOVARTIS at a dose of 10 mg per day for 10 days, and intervention group 2 will receive a dose of 18 mg of Matoraid manufactured by SALUTAS PHARMA GMBH per day for 10 days prior to going to school.

Main outcome variables

The child's performance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041638N1**
Registration date: **2019-02-19, 1397/11/30**
Registration timing: **prospective**

Last update: **2019-02-19, 1397/11/30**
Update count: **0**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Sahar Saadatmand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Survey on short-acting methylphenidate (Ritalin) vs. long-acting methylphenidate (Matoride) effectiveness on Attention deficit Hyperactivity Disorder symptom among 6 - 18 year-old children

Public title
Effectiveness of Matoride in Attention deficit - Hyperactivity disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirm the diagnosis of ADHD based on DSM-5 by pediatric psychiatrist Abscence of other major psychiatric disorder Being at least the age of 6 and maximum age of 18 years old Satisfaction of the inclusion by the parent or guardian of the patient
Exclusion criteria:
The lack of cooperation of the patient and family in order to make the full intervention Receive other drugs, except Matoride and Ritalin A medical condition that prevents use of the drugs Severe hypersensitivity to the drug
Age
From **6 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Randomization block, randomization unit: Individual, Random layer: not done Randomization, tool: Random sequence generation software (Excel), How to create random sequence: Using random blocks, each block contains 4 people And assign a number from 1 to 6 to each block
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients are not aware of the drug and the drug is given to them by the collector in sealed packages. The packets will be properly coded by the researcher before being available to the data collector. The drug distributor will also not be aware of the medication in the package.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commitee of Isfahan University of Medical Sciences
Street address
Ethics Commitee of Isfahan University of Medical Sciences, Research Vice Department, Isfahan Medical University, Hezar Jarib university, Isfahan, Iran.
City
Esfahan
Province
Isfehan
Postal code
8145831451
Approval date
2018-10-04, 1397/07/12
Ethics committee reference number
IR.MUI.MED.REC.1397.058

Health conditions studied

1

Description of health condition studied
Attention deficit - Hyperactivity disorder
ICD-10 code
F90.9
ICD-10 code description
Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description
The child's performance
Timepoint
every day after school will be evaluate.
Method of measurement
Parents' Conners' questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group in which patients will receive 10 mg per day of Ritalin Manufactured by NOVARTIS every morning before the school for ten days.

Category

Treatment - Drugs

2

Description

Intervention group 2: A group of patients will receive 18 mg per day of Matoride manufactured by SALUTAS PHARMA GMBH every morning before the school for ten days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Psychology Clinic, Special Clinic of Khorshid Hospital

Full name of responsible person

Sahar Saadatmand

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Pediatric Psychology Clinic, Special Clinic of Khorshid Hospital, Isfahan University of Medical Sciences, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoe Javanmard

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Vice chancellor for research, Isfahan University of Medical Sciences; Faculty of Medicine; Isfahan University of Medical Sciences; Hezar-Jarib Street; Isfahan; Iran

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Javad Tarahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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
Yes - There is a plan to make this available

Title and more details about the data/document
All data will be available.

When the data will become available and for how long
The start of the access time is immediately after the relevant article is publish.

To whom data/document is available
All people can access the data.

Under which criteria data/document could be used
All analyzes needed can be done on data, and all individuals can apply for data.

From where data/document is obtainable
Applicants can contact the phone number 09138325471 to receive the data

What processes are involved for a request to access data/document
The data will be available to the applicant as soon as possible.

Comments