

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Ropinirole as an adjuvant therapy with methylphenidate in the treatment of ADHD in children: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Evaluating the efficacy of Ropinirole for the treatment of ADHD

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed on patients attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: ADHD diagnosis based on DSM5 - Children between 6-17 years old. Exclusion criteria: Presence of severe medical illness, neurological problems and problems requiring surgery - Presence of any concomitant psychiatric disorder that requires treatment with psychiatric drugs except ODD - History of treatment with ropinirole in the three months prior to the study - Consumption neuroleptic medication in the last 6 months - Weight less than 13.5 kg - Mental retardation - Uncontrolled seizure disorder - Systolic blood pressure above 125 mm Hg or Resting pulse rate less than 60 beats per minute or above 115 beats per minute - Using any medicine or supplement for the treatment of ADHD - History of allergy to methylphenidate or ropinirole

Intervention groups

Control group: Ritalin, 0.1-3.5 mg per kg of body weight, for the first week, one tablet daily (1.2 tablets at the morning, 1.2 tablets at the noon), and for the second week, one tablet at the morning and one tablet at the noon. If the patient's weight is over 30 kg, three pills are prescribed daily, 1 at the morning, 1 at the noon, and 1 at the afternoon (4 p.m.), from the third week. Placebo is prescribed twice a day. Total duration of treatment is 8 weeks. Intervention group: Ritalin (like control group). Ropinirole is prescribed at a dose of 0.25 mg twice a day. Total duration of treatment is 8 weeks.

Main outcome variables

Severity of ADHD symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N151**

Registration date: **2023-06-19, 1402/03/29**

Registration timing: **prospective**

Last update: **2023-06-19, 1402/03/29**

Update count: **0**

Registration date

2023-06-19, 1402/03/29

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ropinirole as an adjuvant therapy with methylphenidate in the treatment of ADHD in children: A randomized, double-blind, placebo-controlled clinical trial

Public title

The efficacy of Ropinirole in the improvement of ADHD

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ADHD diagnosis based on DSM5 Children between 6-17 years old.

Exclusion criteria:

Presence of severe medical illness, neurological problems and problems requiring surgery Presence of any concomitant psychiatric disorder that requires treatment with psychiatric drugs except ODD History of treatment with ropinirole in the three months prior to the study Consumption neuroleptic medication in the last 6 months Weight less than 13.5 kg Mental retardation Uncontrolled seizure disorder Systolic blood pressure above 125 mm Hg or Resting pulse rate less than 60 beats per minute or above 115 beats per minute Using any medicine or supplement for the treatment of ADHD History of allergy to methylphenidate or ropinirole

Age

From **6 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of School of Medicine, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-04-11, 1402/01/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.151

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

ADHD

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

Primary outcomes**1****Description**

Severity of ADHD

Timepoint

Weeks: 0 , 4 , 8

Method of measurement

By ADHD Rating Scale (by parents or teacher)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Ritalin, 0.1-3.5 mg per kg of body weight. For the first week, one tablet daily (1.2 tablets at the morning, 1.2 tablets at the noon), and for the second week, one tablet at the morning and one tablet at the noon. If the patient's weight is over 30 kg, three pills are prescribed daily, 1 at the morning, 1 at the noon, and 1 at the afternoon (4 p.m.), from the third week. Placebo is prescribed twice a day. Total duration of treatment is 8 weeks.

Category

Placebo

2

Description

Intervention group: Ritalin, 0.1-3.5 mg per kg of body weight. For the first week, one tablet daily (1.2 tablets at the morning, 1.2 tablets at the noon), and for the second week, one tablet at the morning and one tablet at the noon. If the patient's weight is over 30 kg, three pills are prescribed daily, 1 at the morning, 1 at the noon, and 1 at the afternoon (4 p.m.), from the third week. Ropinirole is prescribed at a dose of 0.25 mg twice a day. Total duration of treatment is 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Dr. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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Tehran

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1333715914

Phone

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Email

mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

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afotouhi@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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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

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2023 to 2028

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Users should cite the resource of data

From where data/document is obtainable

Prof. Shahin Akhondzadeh

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

By e-mail

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

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