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)

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+98 21 5541 2222

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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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Tehran

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1333715914

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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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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Roozbeh Hospital, South Kargar Street, Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Position
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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
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