

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

: efficacy of extended- release methylphenidate on theory of mind ability of 7-9year old children with attention-deficit hyperactivity disorder.

Protocol summary

Study aim

Efficacy of methylphenidate on ability of theory of mind in children with ADHD

Design

Patients will randomly be selected from 30 patients referred to the ADHD clinic and studied.

Settings and conduct

This is a clinical trial study performed at Imam Hossein Hospital in Tehran. Thirty patients with ADHD who meet the inclusion criteria will be pre-tested with the Hutchin`s Theory of mind Questionnaire (for parents) and the children's TOM test. Diagnosis is based on parental history and then clinical interview and K-SADS. The severity of the disorder is calculated with the ADHD-RS followed by the Hutchin`s and TOM tests.

Participants/Inclusion and exclusion criteria

Ages 7 to 9 years old Having DSM-4 criteria for the diagnosis of ADHD based on K-SADS Having parental consent to participate in the research No history of medication for the disorder

Intervention groups

Children with ADHD will be treated with slow-release methylphenidate for 4 weeks. Questionnaires will be completed before and after one month of treatment.

Main outcome variables

The potential effects of current ADHD therapies on theory of mind have not been adequately explored. Given the prevalence of ADHD and the development of psychosocial complications at different stages of development, the association of the disorder with the theory of the mind and the inability to communicate socially and express emotion empathy with others, This study aimed to determine the effect of methylphenidate on the ability of the theory of mind in children aged 7 to 9 years with attention deficit hyperactivity disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190827044633N1**
Registration date: **2020-04-22, 1399/02/03**
Registration timing: **retrospective**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

Ghadir Mohammad Hoseiny Biareh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 74 3323 3457

Email address

ghmhoseiny@mail.sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: efficacy of extended- release methylphenidate on theory of mind ability of 7-9year old children with attention-deficit hyperactivity disorder.

Public title

efficacy of extended- release methylphenidate on theory of mind ability of 7-9year old children with attention-deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 7 and 9 years old - - Diagnostic and Statistical Manual-4 criteria for diagnosis of attention-deficit hyperactivity disorder Parental consent to participate in research Lack of history of medication for the disorder

Exclusion criteria:

Wechsler's IQ of less than 91 based on Wechsler's test - - other major psychiatric illnesses including ASD any physical defects that prevent tests, including severe visual and hearing impairment

Age

From **7 years** old to **9 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

3rd floor,Collage of medicine,Next to Taleghani hospital,Evin,Chamran highway,Tehran

City

Tehran

Province

Tehran

Postal code

1651976341

Approval date

2019-12-29, 1398/10/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.495

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

Attention Deficit/ Hyperactivity Disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attentionAttention deficit:disorder with hyperactivityhyperactivity disordersyndrome with hyperactivityExcl.:hyperkinetic disorder associated with conduct disorder (F90.1)

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

Score in the Hutchin's Theory of Mind Questionnaire

Timepoint

At baseline and one month after treatment with long-acting methylphenidate.

Method of measurement

Hutchin`s Theory of Mind Questionnaire

2**Description**

Score in the TOM(Theory of Mind) test

Timepoint

At baseline and one month after treatment with long-acting methylphenidate.

Method of measurement

TOM(Theory of Mind) test

3**Description**

score in Attention Deficit Hyperactivity Disorder Rating scale

Timepoint

At baseline and one month after treatment with long-acting methylphenidate.

Method of measurement

Attention Deficit Hyperactivity Disorder Rating scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients with Attention Deficit Hyperactivity Disorder receive long-acting

methylphenidate 18 mg tablets, manufactured by Sandoz, at a dose of 0.6-1.2 mg / kg, orally, once daily for one month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Rozita Davari Ashtiani

Street address

Psychiatry Department,Imam Hussein Hospital,Madani street,Tehran,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rozita Davari Ashtiani

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Psychiatry Department,Imam Hosein Hospital.Tehran,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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rozita Davari Ashtiani

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Possibility of publication in some specific journals

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available