

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Ritalin on the influence of emotion on behavioral inhibition in 8 to 12 years old boys with attention deficit hyperactivity disorder

Protocol summary

Study aim

Determining the effect of Ritalin on the influence of emotion on behavioral inhibition in children with Attention Deficit Hyperactivity Disorder (ADHD), Determining the effect of Ritalin on performance improvement in Emotional stroop test and Affective go/no go test tasks in children with ADHD, Comparison of the performance of children with ADHD and children with normal development in the Emotional stroop test and Affective go / no go test

Design

25 boys with ADHD admitted to the Roozbeh Hospital Child Psychiatric Clinic, and 20 boys without any psychiatric disorders entered the trial on the basis of invitation

Settings and conduct

Conducting interview and completing questionnaires (by a psychiatrist) and performing intelligence test (by a psychologist) and then performing two computer tests (Emotional stroop test and Affective go/ no go) in Roozbeh Hospital Cognitive Science Research Center and repeating that two tests again in ADHD group, 6 weeks after receiving Ritalin

Participants/Inclusion and exclusion criteria

Inclusion criteria: Boys 8 to 12 years old with IQ above 70, without a history of taking medicine in a recent month, typical development participants: Absence of any psychiatric disorder or medical disease, ADHD participants : Diagnosis of ADHD, and no other psychiatric disorders except to oppositional defiant disorder Diagnosis is based on history taking and interview and K-SADS and the Connors questionnaire. Exclusion criteria: Items other than inclusion criteria

Intervention groups

Start Ritalin treatment in ADHD group, after taking Emotional stroop test and Affective go no go. After 6 weeks of Ritalin treatment, retake the two tests.

Main outcome variables

Reaction time, Error rate, Affective go/no go commission error, Affective go/no go omission error, Emotional stroop test commission error, Emotional Stroop test omission error

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050450N1**
Registration date: **2021-10-27, 1400/08/05**
Registration timing: **retrospective**

Last update: **2021-10-27, 1400/08/05**

Update count: **0**

Registration date

2021-10-27, 1400/08/05

Registrant information

Name

Arghavan Fariborzifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8881 2497

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

2020-09-28, 1399/07/07

Actual recruitment end date

2021-07-06, 1400/04/15

Trial completion date

2021-08-23, 1400/06/01

Scientific title

Evaluation of the effect of Ritalin on the influence of emotion on behavioral inhibition in 8 to 12 years old boys with attention deficit hyperactivity disorder

Public title

Evaluation of the effect of Ritalin on the influence of emotion on behavioral inhibition in children with ADHD

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 8 to 12 years History of not taking psychotropic drug in a recent month, In the group of ADHD participants: Diagnosis of ADHD based on interview and history and K-SADS and Conners Parent Questionnaire, conducted by a psychiatrist

Exclusion criteria:

IQ based on Wechsler Intelligence Scale for Children (WISC) 4, below 70 In the group of participants Typical development: the presence of any psychiatric disorder or medical illness, which prevents them from participating in the test or causes changes in attention or mood changes in them, based on taking a history and interview and K-SADS and Conners Parent Questionnaire, performed by a psychiatrist In the group of ADHD participants: the presence of other psychiatric disorders comorbid with ADHD (except oppositional defiant disorder) or the presence of any medical illness that prevents participants from participating in the test or causes a change in attention or mood changes in them The child's unwillingness to participate in the study or the guardian's dissatisfaction with the child's participation in the study

Age

From 8 years old to 12 years old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 45

Actual sample size reached: 45

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

13th floor, Block A, Headquarters of the Ministry of Health, Treatment and Medical Education, Simaye_iran St, Ghods Town (West) - between South Falamak and Zarafshan, Tehran

City

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Province

Tehran

Postal code

1467674475

Approval date

2020-09-19, 1399/06/29

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.463

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

Attention Deficit Hyperactivity Disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

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

1.Mean reaction time in Affective go no go test

Timepoint

At the beginning of the study and 6 weeks after starting Ritalin in the ADHD group

Method of measurement

Affective go no go test computer software

2**Description**

2. Mean reaction time in emotional stroop test

Timepoint

At the beginning of the study and 6 weeks after starting Ritalin in the ADHD group

Method of measurement

Emotional stroop test computer software

3

Description

3.Affective go/no go commission error

Timepoint

At the beginning of the study and 6 weeks after starting Ritalin in the ADHD group

Method of measurement

Affective go no go test computer software

4

Description

4.Affective go/no go omission error

Timepoint

At the beginning of the study and 6 weeks after starting Ritalin in the ADHD group

Method of measurement

Affective go no go test computer software

5

Description

5.Emotional stroop test commission error

Timepoint

At the beginning of the study and 6 weeks after starting Ritalin in the ADHD group

Method of measurement

Emotional stroop test computer software

6

Description

6.Emotional Stroop test omission error

Timepoint

At the beginning of the study and 6 weeks after starting Ritalin in the ADHD group

Method of measurement

Emotional stroop test computer software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Twenty-five boys diagnosed with ADHD who had not received any psychotropic drugs for at least one month. After performing emotional stroop test and affective go no go, treatment with Ritalin (starting with 0.5 mg / kg in three divided doses and increasing the dose after 5 days to 1 mg / kg (2/3 doses in the morning and noon and 1/3 is given at 4 pm), starts in them and continues for 6 weeks, after 6 weeks the emotional stroop test and affective go no go are taken again.

Category

Treatment - Drugs

2

Description

Control group: 20 boys without any psychiatric disorders who perform emotional stroop test and affective go no go.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Mehdi Tehranidoost

Street address

Department of Psychiatry, School of Medicine
Research Center for Cognitive and Behavioral
Sciences, Roozbeh Hospital, Tehran University of
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

Keshavarz Boulevard, corner of Quds Street, Central
University Organization, sixth floor, Vice Chancellor
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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

Tehran University of Medical Sciences

Proportion provided by this source

10

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

Arghavan Fariborzifar

Position

Child and Adolescent Psychiatry Fellowship

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Professor of Child and Adolescent Psychiatry

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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

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Full name of responsible person

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Position

ChiChild and Adolescent Psychiatry Fellowship

Latest degree

Specialist

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

There is no further information

Study ProtocolUndecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**Undecided - It is not yet known if there will be 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**Undecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**

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

make this available