Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
Phone
+98 21 8881 2497
Email address
a.fariborzifar@yahoo.com

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
Tehran
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 Medical Sciences
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 9151
Fax
+98 21 5541 9113
Email
tehranid@sina.tums.ac.ir

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 for Research and Technology
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
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
Street address
No. 90, 3rd Floor, Kakh Building, Kakh Crossroads, 11th Mountain Alley, Head of Soroush Street, Ahmadabad Square, Isfahan City, Isfahan Province
City
Isfehan
Province
Isfehan
Postal code
8199653888
Phone
+98 31 3250 5466
Email
a.fariborzifar@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mehdi Tehranidoost
Position
Professor of Child and Adolescent Psychiatry
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Department of Psychiatry, School of Medicine Research Center for Cognitive and Behavioral Sciences, Roozbeh Hospital, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 5541 9151
Email
tehranid@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Arghavan Fariborzifar
Position
ChiChild and Adolescent Psychiatry Fellowship
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No. 90, Corner of Kakh Intersection, 11 Shahid Koohi Alley, Soroush St., Ahmadabad Sq., Isfahan
City
Isfehan
Province
Isfehan
Postal code
8199653888
Phone
+98 31 3250 5466
Email
a.fariborzifar@yahoo.com

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 Protocol
Undecided - 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