

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Methylphenidate on neural correlate of understanding intentionality in children with attention-deficit hyperactivity disorder {ADHD}

Protocol summary

Study aim

Evaluation of the effect of Methylphenidate on neural correlate of understanding intentionality in children with attention-deficit hyperactivity disorder(ADHD)

Design

The before-after study without a control group and the study' phase is 4 with the participation of twenty patients. In the present study, convenience sampling is used. All children and adolescence with ADHD are selected according to inclusion criteria from those who refer to the Psychiatric Clinic of Tehran Roozbeh hospital.

Settings and conduct

Neuroimaging (fMRI) will be performed at the National Brain Mapping Laboratory. Other stages of the study will be performed at Roozbeh Psychiatric Hospital in Tehran. The patients will be selected based on the psychiatrist's diagnosis. The intelligence quotient (IQ) will be performed by a clinical psychologist. For all the subjects, baseline assessment of disorder severity and dimensions, clinical interview, neurocognitive assessments will be done. Neurocognitive assessment and fMRI will be reoperate six-weeks after starting the treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ADHD diagnosis; Male sex; Age 8 to12 years; IQ more than 90 according to Wechsler Intelligence Scale, Exclusion criteria: Major psychiatric disorders; Neurologic disorders; Major medical disorders; Taking medications that affect the central nervous system; substance abuse

Intervention groups

This study has an intervention group without a control group. Intervention group have ADHD and receive six weeks of medication with Methylphenidate 0.5 -1mg/kg/day divided into three daily doses. Magnetic resonance brain imaging (fMRI) and cognitive assessments (cognitive Tasks and questionnaires) will be

performed before and six weeks after the start of treatment.

Main outcome variables

Neural correlate of understanding intentionality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201103049254N1**

Registration date: **2020-12-28, 1399/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-28, 1399/10/08**

Update count: **0**

Registration date

2020-12-28, 1399/10/08

Registrant information

Name

Shahrbano Ghodrati-Jaldbakhan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4305 2000

Email address

sh-ghodrati@farabi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-03, 1399/07/12

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Methylphenidate on neural correlate of understanding intentionality in children with attention-deficit hyperactivity disorder {ADHD}

Public title
Effect of Methylphenidate on understanding intentionality in ADHD children

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
ADHD diagnosis according to Diagnostic and Statistical Manual of Mental Disorders, 5th Edition Male sex Age 8-12 years IQ more than 90 according to Wechsler Intelligence Scale
Exclusion criteria:
Major psychiatric disorders Neurologic disorders Major medical disorders Taking medications that affect the central nervous system substance abuse

Age
From **8 years** old to **12 years** old

Gender
Male

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **20**

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 Tehran University of Medical Sciences
Street address
NO. 88, Department of Neurosciences and Addiction

Studies, Ninth floor, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417755469

Approval date
2019-12-22, 1398/10/01

Ethics committee reference number
IR.TUMS.VCR.REC.1398.735

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

Changes in the activity of brain regions related to the undrestanding intentionality

Timepoint

Before, and six weeks after starting the treatment with Methylphenidate

Method of measurement

Fanctional magnetic resonance brain imaging (fMRI)

Secondary outcomes

1

Description

Ability of response inhibition

Timepoint

Before and six weeks after starting the treatment with Methylphenidate

Method of measurement

Stop-Signal task by Cambridge Neuropsychological Test Automated Battery (CANTAB)

2

Description

Severity of core symptoms of attention deficit-hyperactivity disorder

Timepoint

Before and six weeks after starting the treatment with Methylphenidate

Method of measurement

Conners' Parent Rating Scale (Questionnaire)

3

Description

The effects of symptoms on behavior in terms of family, education, social and psychological

Timepoint

Before and six weeks after starting the treatment with Methylphenidate

Method of measurement

Children's Global Assessment Scale

Intervention groups

1

Description

Intervention group: participants have ADHD and receive six weeks of medication with Methylphenidate 0.5 -1mg/kg/day divided into three daily doses (1mg per kg maximum dosage). In this study Methylphenidate tablets (Novartis company) are used. To evaluate the effect of Methylphenidate on neural correlate of understanding intentionality, magnetic resonance brain imaging (fMRI) and cognitive assessments (cognitive Tasks and questionnaires) will be performed before and six weeks after the start of treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Mehdi Tehrani-Doost

Street address

Roozbeh hospital, South Kargar Street, Tehran , Iran

City

Tehran

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1333715914

Phone

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Fax

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Email

hosp_roozbeh@tums.ac.ir

Web page address

<http://roozbehhospital.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Sixth Floor, Central Organization of Tehran University of Medical Science, Qods Street

City

Tehran

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Tehran

Postal code

3439123900

Phone

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Email

tums_edu@tums.ac.ir

Web page address

<http://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

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. Mehdi Tehrani-Doost

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Roozbeh Hospital, South Kargar Street, Tehran , Iran

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1333715914

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehdi Tehrani-Doost

Position

Professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahrbano Ghodrati-Jaldbakhan

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Neuroscience

Street address

N0. 88, Department of Neurosciences and Addiction Studies, Ninth floor, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran, Iran

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Fax

Email

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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

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

Not applicable

Title and more details about the data/document

Information of the main (primary outcome) and the secondary outcomes like neuronal networks reorganization outcome and cognitive assessments can be shared.

When the data will become available and for how long

6 months after publication of results

To whom data/document is available

Research data will be available for the researchers of universities and scientific institutes.

Under which criteria data/document could be used

The data will be available when the samples are taken out, all the stages of the project are completed and finalized, and the results are published.

From where data/document is obtainable

Dr. Mehdi Tehrani-Doost Tehranid@tums.ac.ir

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

In order to receive the information, firstly the applicants send the formal application to the correspondent of the present proposal, Dr. Mehdi Tehrani-Doost, and then they will be informed of the details of the data reception (including timing and the way of addressing the available data like email or in-person).

Comments