evaluation of the effect of methylphenidate on prefronto-cerebellar neurometabolites in children and adolescence with attention deficit hyperactivity disorder: a proton magnetic resonance spectroscopy study

Protocol summary

Study aim
The aim of this study is to investigate the effect of methylphenidate on prefronto-cerebellar neurometabolites in children and adolescence with ADHD.

Design
All children and adolescence with ADHD were selected according to inclusion criteria from the out patient department of Tehran Roozbeh hospital. The control group were recruited from children and adolescence of Tehran schools. This study’ phase is 3 as mentioned above. In the present study the convenience sampling were used.

Settings and conduct
This study is ongoing at the National Brain Mapping laboratory. cognitive assessments and brain scan were done before and after medication. All assessors of evaluation sections were unaware of participants profile and status.

Participants/Inclusion and exclusion criteria
-Age between 8-13 years -Normal IQ according to Wechsler Intelligence Scale -Attention Deficit Hyperactivity Disorder diagnosis according to DSM-V - Absence of medication usage history -Absence of any neurologic, psychiatric, brain trauma and other medical diagnosis

Intervention groups
This study consist of one treatment and one control group. Treatment group received brain scan and cognitive assessments before and after 8-week-medication with methylphenidate. The control group in this study normal were children and adolescence and received only single scan and a session of cognitive assessment.

Main outcome variables
Main outcome variables in the present study are neurometabolites (creatine, choline and N-Acetyl Aspartate), CANTAB (RVP,SWM) variables, IVA variable, behavioral variables of ADHD-RS and Conners Rating Scale.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20201105049271N1
Registration date: 2020-11-25, 1399/09/05
Registration timing: registered_while_recruiting

Last update: 2020-11-25, 1399/09/05
Update count: 0
Registration date
2020-11-25, 1399/09/05
Registrant information
Name
Soroush Bakhshi
Name of organization / entity
Institute for cognitive science studies
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-07-23, 1398/05/01
Expected recruitment end date
2021-07-23, 1400/05/01
Actual recruitment start date
Actual recruitment end date  
Trial completion date  
Scientific title  
evaluation of the effect of methylphenidate on prefronto-cerebellar neurometabolites in children and adolescence with attention deficit hyperactivity disorder: a proton magnetic resonance spectroscopy study  
Public title  
evaluation of the effect of methylphenidate in children and adolescence with attention deficit hyperactivity disorder  
Purpose  
Treatment  
Inclusion/Exclusion criteria  
Inclusion criteria:  
Attention deficit hyperactivity disorder diagnosis without comorbidity Drug-naive at the age of 8 Normal IQ Boy age between 8 to 13 years old  
Exclusion criteria:  
Any medical and psychiatric disorder comorbidity Taking medication before the age of eight  
Age  
From 8 years old to 13 years old  
Gender  
Male  
Phase  
3  
Groups that have been masked  
No information  
Sample size  
Target sample size: 30  
Randomization (investigator's opinion)  
Not randomized  
Randomization description  
Blinding (investigator's opinion)  
Not blinded  
Blinding description  
Placebo  
Not used  
Assignment  
Parallel  
Other design features  
In the present study, participants in the treatment group were selected according to inclusion criteria and among Roozbeh out-patient clients with ADHD. The control group were selected from Tehran schools (with parental consent).  
Secondary Ids  
empty  
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  
Creatine: A neurometabolite wich is marker of energy metabolism  
Timepoint  
Before and after 8 week medication  
Method of measurement  
Magnetic resonance spectroscopy  
2. Description  
Choline: A neurometabolite wich is marker of membrane integrity  
Timepoint  
Before and after 8 week medication  
Method of measurement  
Magnetic resonance spectroscopy  
3. Description  
N-acetyl aspartate: A neurometabolite wich is marker of neural health  
Timepoint  
Before and after 8 week medication  
Method of measurement  
Magnetic resonance spectroscopy  
Ethics committees  
1. Ethics committee  
Name of ethics committee  
Ethic committee of Shahid Beheshti university of medical sciences  
Street address  
No39, Monsef Alley, Esteghamat St, Rasht, Guilan  
City  
Rasht  
Province  
Guilan  
Postal code  
4144953815  
Approval date  
2019-07-07, 1398/04/16  
Ethics committee reference number  
IR.SBMU.RETECH.REC.1398.158
Mean latency in Rapid Visual Information Processing Test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
CANTAB computerized test

5

**Description**
Total Hits in Rapid Visual Information Processing Test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
CANTAB computerized test

6

**Description**
Total correct rejections in Rapid Visual Information Processing Test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
CANTAB computerized test

7

**Description**
Strategy in Spatial Working Memory Test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
CANTAB computerized test

8

**Description**
Between errors in Spatial Working Memory Test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
CANTAB computerized test

9

**Description**
Within errors in Spatial Working Memory Test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
CANTAB computerized test

10

**Description**
Visual vigilance in IVA test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test

11

**Description**
Auditory vigilance in IVA test

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test

12

**Description**
Focus in IVA test (Visual)

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test

13

**Description**
Focus in IVA test (Auditory)

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test

14

**Description**
Speed in IVA test (Visual)

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test

15

**Description**
Speed in IVA test (Auditory)

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test

16

**Description**
Prudence in IVA test (Visual)

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test

17

**Description**
Prudence in IVA test (Auditory)

**Timepoint**
Before and after 8 week medication

**Method of measurement**
IVA computerized test
18
Description
Consistency in IVA test (Visual)
Timepoint
Before and after 8 week medication
Method of measurement
IVA computerized test

19
Description
Consistency in IVA test (Auditory)
Timepoint
Before and after 8 week medication
Method of measurement
IVA computerized test

20
Description
Stamina in IVA test (Visual)
Timepoint
Before and after 8 week medication
Method of measurement
IVA computerized test

21
Description
Stamina in IVA test (Auditory)
Timepoint
Before and after 8 week medication
Method of measurement
IVA computerized test

22
Description
Inattention subscale (ADHD Rating Scale)
Timepoint
Before and after 8 week medication
Method of measurement
ADHD Rating Scale

23
Description
Hyperactivity/impulsivity subscale (ADHD Rating Scale)
Timepoint
Before and after 8 week medication
Method of measurement
ADHD Rating Scale

24
Description
Total score in ADHD Rating Scale
Timepoint
Before and after 8 week medication
Method of measurement
ADHD Rating Scale

25
Description
Oppositional subscale of Conners Parent Rating Scale
Timepoint
Before and after 8 week medication
Method of measurement
Conners Parent Rating Scale

26
Description
Inattention/cognitive problems subscales of Conners Parent Rating Scale
Timepoint
Before and after 8 week medication
Method of measurement
Conners Parent Rating Scale

27
Description
Hyperactivity/impulsivity subscale of Conners Parent Rating Scale
Timepoint
Before and after 8 week medication
Method of measurement
Conners Parent Rating Scale

28
Description
ADHD index of Conners Parent Rating Scale
Timepoint
Before and after 8 week medication
Method of measurement
Conners Parent Rating Scale

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: participants in this group have ADHD and received 8-weeks medication with methylphenidate three times a day (1mg per kg maximum dosage) that were began from 0.3-0.5 mg per kg. In this study Ritalin (Novartis company) was used.
Category
Treatment - Drugs

2
Description
Control group: This group were normal children and adolescence that received only one assessment (single scan and cognitive assessment) session.
Category
N/A
Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran's Roozbeh hospital-outpatient children and adolescence department

Full name of responsible person
Soroush Bakhshi

Street address
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Tehran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Institute for Cognitive Science Studies

Full name of responsible person
Javad Hatami

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Province
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Email
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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
Institute for Cognitive Science Studies

Proportion provided by this source
5

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
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Professor of Psychiatry

Latest degree
Subspecialist

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Assistant Professor

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Tehran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

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
No - There is not a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The present study is ongoing. The part of data that is useful in related studies, will be available.

When the data will become available and for how long
6 month after the paper publication

To whom data/document is available
The data will be available only for collegiate researchers

Under which criteria data/document could be used
The data utilization will be allowed with the citation exclusively

From where data/document is obtainable
Contact information for data utilization:
00989123707980 bakhshi_s@iricss.org

What processes are involved for a request to access data/document
Request forwarding with collegiate documentation via phone or e-mail

Comments