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

Registrant information
Name
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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
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

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

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Rasht

Province
Guilan

Postal code
4144953815

Approval date
2019-07-07, 1398/04/16

Ethics committee reference number
IR.SBMU.RETECH.REC.1398.158

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 which is marker of energy metabolism

Timepoint
Before and after 8 week medication

Method of measurement
Magnetic resonance spectroscopy

2

Description
Choline: A neurometabolite which 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 which is marker of neural health

Timepoint
Before and after 8 week medication

Method of measurement
Magnetic resonance spectroscopy
<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Description</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before and after 8 week medication</td>
<td>Mean latency in Rapid Visual Information Processing Test</td>
<td>CANTAB computerized test</td>
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<tr>
<td>Total Hits in Rapid Visual Information Processing Test</td>
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<tr>
<td>Before and after 8 week medication</td>
<td>Total correct rejections in Rapid Visual Information Processing Test</td>
<td>CANTAB computerized test</td>
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<tr>
<td>Strategy in Spatial Working Memory Test</td>
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<tr>
<td>Before and after 8 week medication</td>
<td>Between errors in Spatial Working Memory Test</td>
<td>CANTAB computerized test</td>
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<tr>
<td>Within errors in Spatial Working Memory Test</td>
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<tr>
<td>Before and after 8 week medication</td>
<td>Visual vigilance in IVA test</td>
<td>IVA computerized test</td>
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<tr>
<td>Auditory vigilance in IVA test</td>
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<tr>
<td>Focus in IVA test (Visual)</td>
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<tr>
<td>Before and after 8 week medication</td>
<td>Focus in IVA test (Auditory)</td>
<td>IVA computerized test</td>
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<tr>
<td>Speed in IVA test (Visual)</td>
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<tr>
<td>Speed in IVA test (Auditory)</td>
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<td>Prudence in IVA test (Visual)</td>
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<tr>
<td>Prudence in IVA test (Auditory)</td>
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</tbody>
</table>
## 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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Email
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Web page address
http://roozbehhospital.tums.ac.ir/

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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Email
ICSS@iricc.org
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
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Assistant Professor

Latest degree
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Other areas of specialty/work
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Street address
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City
Tehran

Province
Tehran

Postal code
1413379141

Phone
009866581535

Email
batouli@sina.tums.ac.ir

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