Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Methylphenidate and Atomoxetine Combination Therapy in the Treatment of Children with Hyperactivity Disorder - Attention Deficit with Relative Response to Single Medicinal Therapy

Protocol summary

Study aim
Comparison of the effect of Ritalin and Atomoxetine therapy and Ritalin-Atomoxetine combination in the treatment of hyperactivity-disordered children
Design
A randomized, concealed, double blinded, without control, without parallel
Settings and conduct
double blinded, Children with ADHD in Ibn-e-Sina Hospital of Mashhad, at 1397
Participants/Inclusion and exclusion criteria
1. Children with ADHD based on DSM5 2. Age of 6-17 years 3. People who are not under any medication or non-pharmacological treatment of any other concomitant mental illness. 4. People who do not have chronic medical conditions, such as cardiovascular disease. 5. IQ more than 70 6. Lack of organic brain dysfunction 7. If having a seizure disorder, be treated and controlled. 8. Lack of previous diagnosis of mental illness such as psychosis, bipolar disorder, schizoaffective, schizophrenia, unipolar depression, panic or GAD 9. No Tourette Disorder
Intervention groups
ADHD children with CGI score of 3, 4 and 5
Main outcome variables
Progress in social and home functions

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190526043708N1**
Registration date: **2019-12-23, 1398/10/02**
Registration timing: **retrospective**

Last update: **2019-12-23, 1398/10/02**
Update count: **0**
Registration date
2019-12-23, 1398/10/02

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-07-21, 1397/04/30
Expected recruitment end date
2019-03-20, 1397/12/29
Actual recruitment start date
2018-07-21, 1397/04/30
Actual recruitment end date
2019-03-20, 1397/12/29
Trial completion date
2019-05-20, 1398/02/30

Scientific title
The Effect of Methylphenidate and Atomoxetine Combination Therapy in the Treatment of Children with Hyperactivity Disorder - Attention Deficit with Relative Response to Single Medicinal Therapy

Public title
The effect of combination therapy of methylphenidate and Atomoxetine in the treatment of hyperactivity-disordered children

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ADHD aged 6-17 years patients who are not treated concurrently with medicinal or non-drug therapy IQ of more than 70
Exclusion criteria:
Family dissatisfaction with continued treatment Incidence of side effects
Age
From **6 years** old to **17 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **24**
Actual sample size reached: **22**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, main researcher
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of mashad University of Medical Sciences
Street address
At the beginning of Hore Amali Street, Avicenna Hospital
City
mashad
Province
Razavi Khorasan
Postal code
9196634539
Approval date
2018-07-18, 1397/04/27
Ethics committee reference number
ir.mums.fm.rec.1396.237

Health conditions studied

1

Description of health condition studied
Attention Deficit Hyperactivity Disorder
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Parents' ADHD/RS Score
Timepoint
0 and 4 weeks later
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with attention deficit hyperactivity disorder were divided into two groups, half of them were treated with 4 weeks of atomoxetine and the other half were treated with 4 weeks of ritalin. The dose of atomoxetine was started 0.5 mg / kg daily before bedtime with snacks and then up to 1.4 mg / kg daily - the maximum dose was 100 mg twice daily, depending on patient tolerance. The dose of ritalin was increased to 0.5 mg / kg up to a maximum of 1 mg / kg daily divided by patient tolerance. Patients with partial response were subsequently treated with combination ritalin and atomoxetine for 4 weeks at the same dose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn-e-Sina Hospital
Full name of responsible person
Paria Hebrani
Street address
Hor-e Ameli Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Azadi Square.
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tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahdi Pourmahmoudian
Position
Resident
Latest degree
Medical doctor
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Psychiatrics
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Age distribution, Sex distributions, Education Grade, ADHD/RS score, CGI score
When the data will become available and for how long
Summer 2019
To whom data/document is available
Researchers
Under which criteria data/document could be used
Advanced studies, use in treatment
From where data/document is obtainable
Mahdi Pourmahmoodian pourmahmoodian.m@gmail.com
What processes are involved for a request to access data/document
Emailing, Authentication
Comments