Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of QEEG(Quantitaive electroencephalography) indices in children with ADHD (Attention deficit hyperactivity disorder)in two groups receiving automoxetine and ritalin

Protocol summary

Study aim
Comparison of the effect of atomoxetine and ritalin on brain wave index changes(QEEG) in ADHD(attention deficit hyperactivity disorder) boy children referred to Tabriz Psychiatric Clinic in the second semester of 1398.

Design
Intervention randomized controlled trial, randomized, without blinding

Settings and conduct
The study is conducted on 7-12 year old boys with severe ADHD (Attention-deficit hyperactivity disorder). These children are referred to the Razi Hospital Psychiatry Clinic. They are divided into two groups. for All children in both groups brainwave indices will be recorded. Then the first group is given Automoxetin for 3 months and the second group is administered Ritalin for 3 months. After 3 months Brainwave indexes are re-recorded for all members of both groups.

Participants/Inclusion and exclusion criteria
inclusion: 1-Obtain informed consent from parents. 2-12-7 years old. 3. IQ greater than 70. 4- Child and adolescent psychiatrist discusses ADHD 5-Boy children exclusive: 1. A history of medication for ADHD 2. Other concurrent psychiatric disorder. 3. Concomitant medical illnesses

Intervention groups
drug treatment in the first group with Atomoxetine and in the second group with Ritalin for 3 months.

Main outcome variables
Changes in brainwave indices.(QEEG)

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20140825018927N7**
Registration date: **2019-12-02, 1398/09/11**
Registration timing: **prospective**

Last update: **2019-12-02, 1398/09/11**
Update count: **0**

Registration date
2019-12-02, 1398/09/11

Registrant information

Name
Seyed Gholamreza Noorazar

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-10, 1398/09/19

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of QEEG(Quantitaive electroencephalography) indices in children with ADHD

(Attention deficit hyperactivity disorder)in two groups receiving automoxetine and ritalin

Public title
Comparison of brainwave indices in overactive children receiving automoxetine and ritalin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
7-12 years old Male gender Parental consent for child participation in research IQ greater than 70 Diagnosis of ADHD by a child and adolescent psychiatrist
Exclusion criteria:
History of medication for ADHD Other psychiatric disorders Existence of medical diseases
Age
From **7 years** old to **12 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to either the Ritalin and the automoxetin treatment groups according to the National Code Number of Participants.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Children7-12 years old with ADHD diagnosed according to DSM-5 criteria and adolescent psychiatrist enter clinical trial after obtaining informed consent from parents about their children's participation in the study and inclusion criteria.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Central campus of Tabriz university of medical science, Golgasht Avenue, Azadi street, Tabriz, Eastern Azarbayjan, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
4535675432
Approval date
2019-08-11, 1398/05/20
Ethics committee reference number
IR.TBZMED.REC.1398.804

Health conditions studied

1

Description of health condition studied
بیش فعالی - نقص توجه
ICD-10 code
F90
ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
brainwave indices
Timepoint
At baseline, 3 months later
Method of measurement
Quantitative electroencephalography (Qualitative brainwave recorder,LORETA)

Secondary outcomes

empty

Intervention groups

1

Description
Children with ADHD, aged 7-12 years, enter the study after obtaining informed consent from parental clinical trial studies and having inclusion and exclusion criteria. Parents' Connors Test is used to determine the severity of the disease.The brain wave markers are recorded for sever disorderes with LORETA QEEG, then the drug treatment with automoxetine at a dose of 0.5-1.8 mg daily is continued for 3 months, then the QEEG is recorded.
Category
Treatment - Drugs

2

Description
Intervention group2: Children with ADHD, aged 7-12 years, enter the study after obtaining informed consent from parental clinical trial studies and having inclusion and exclusion criteria. Parents' Connors Test is used to

determine the severity of the disease.The brain wave markers are recorded for sever disorderes with LPRETA QEEG, then the drug treatment with Ritalin at a dose of 0.3-1 mg daily is continued for 3 months, then the QEEG is recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi medical-educational center

Full name of responsible person

Dr Seyed Gholamreza Noorazar

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EL-GOLI

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5173865955

Phone

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sahar65salimi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ali Fakhari

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Central campus of Tabriz university of medical science, Golgasht Avenue, Azadi street, Tabriz, Eastern Azirbayjan, Iran

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Grant name

Tabriz University of Medical Sciences

Grant code / Reference number

3

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

sahar salimi

Position

psychiatry residency

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Clinical psychiatric research center, Razi educational-medical center, Eil goli street, Tabriz, Eastern Azarbayjan, Iran

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Dr Seyed Gholamreza Noorazar

Position

assistant professor of Psychiatry

Latest degree

Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Will be presented in the article
When the data will become available and for how long
1399
To whom data/document is available
public
Under which criteria data/document could be used
Article and thesis
From where data/document is obtainable
University site
What processes are involved for a request to access data/document
There is no process
Comments