

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of QEEG(Quantitative electroencephalography) indices in children with ADHD (Attention deficit hyperactivity disorder)in two groups receiving atomoxetine 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 Atomoxetine 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(Quantitative electroencephalography) indices in children with ADHD

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

Public title

Comparison of brainwave indices in overactive children receiving atomoxetine 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 atomoxetine 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

Children 7-12 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 Azarbaijan, 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 severe disorders with LORETA QEEG, then the drug treatment with atomoxetine 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 group 2: 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 severe disorders 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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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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