

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of Attentalin and Atomoxetine in treatment of the attention deficit and hyper activity disorder

Protocol summary

Study aim

Comparison of the effect of Attentalin and Atomoxetine in the treatment of patients with ADHD

Design

randomized clinical trial ,double blind, third phase on 46 patients

Settings and conduct

This research is about to be conducted in the field of treatment of psychiatric disorders of children and adolescents . The place where it is performed is the specialized psychiatry clinic of Sina Psychiatric Hospital in Hamedan. After the initial assessment, children aged 6 to 12 with ADHD according to DSM5 criteria were divided into two groups , and medication was prescribed and they will be followed up three times at 0, after 3 weeks and after 6 weeks by ADHD-rating-scale questionnaire One group will receive Attentalin syrup and placebo capsules, and the other group will receive placebo syrup and Atomoxetine capsules.It is a double blind study, researchers and patient are blinded by one of staff of clinic The patients are not aware of the type of medicine used and each group does not know about the other group.

Participants/Inclusion and exclusion criteria

1. Pediatric patient with attention deficit hyperactivity disorder from age 6 to 12 both genders based on dsm 5 criteria 2. Obtaining the informed consent from parents
Exclusion criteria: 1. Children with history of Hyperthyroidism, seizure, eating disorders (anorexia) , glaucoma, 2. substance use disorders 3. Children who used MAOI drugs during recent 15 days. 4. Children with hepatic, cardiac, renal or chronic diseases which have required special care

Intervention groups

we have put patients in two group . one group takes Attentalin syrup and placebo capsule another group takes placebo syrup and Atomoxetine capsule.

Main outcome variables

attention deficit and hyperactivity symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230419057960N1**

Registration date: **2023-10-08, 1402/07/16**

Registration timing: **prospective**

Last update: **2023-10-08, 1402/07/16**

Update count: **0**

Registration date

2023-10-08, 1402/07/16

Registrant information

Name

Atiyeh Majidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3827 1094

Email address

a.majidi@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-05-09, 1403/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Attentalin and Atomoxetin in treatment of the attention deficit and hyper activity disorder

Public title

Comparison the efficacy of Attentalin and Atomoxetin in ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who recieved Attentin Deficite and Hyoeractivity Disorder due to DSM 5 criteria . Obtaining Informed consent from parents Age 6 to 12 years old

Exclusion criteria:

Seizures Glaucoma History of hyperthyroidism Eating disorders (anorexia) Children with a history of liver , kidney , heart diseases or other chronic illnesses requiring care Children who have taken MAOI medication for the 15 days prior to entering the study. substance abuse disorder

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization : we use simple randomization and devided patient to two group A and B

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are divided into two groups, A and B. In one group, Attentalin syrup and placebo capsules are given, and in the other group, placebo syrup and Atomoxetine capsules are given. The patients has no knowledge about the other group, the drugs used and the placebo in the research are given to the patients by one of the clinic personnel with a specific code , so the researchers and the patient do not know the type of drug used. The data obtained from the study of the patients are collected by the researcher and are provided to the analyst and statistician in a private manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Science

Street address

Kasshani

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.UMSHA.REC.1401.1083

Health conditions studied

1

Description of health condition studied

Attention deficit and hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

Symptoms of hyperactivity/attention deficit

Timepoint

before the trial and 3 and 6 weeks later

Method of measurement

ADHD Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: The patient's weight, blood pressure and pulse are measured, physical symptoms and complaints are asked from the patient and parents. In this group, patients are treated with atomoxetine capsules with a starting dose of 0.5 mg per kilogram of weight, then after a week, the dose reaches 1 mg per kilogram of weight and the treatment continues. ADHD RATING SCALE questionnaire will be completed by the psychiatric resident on day zero and in week 3 and 6.

Category

Treatment - Drugs

2

Description

Intervention group B : The patient's weight, blood pressure and pulse are measured, physical symptoms and complaints are asked from the patient and parents. In this group, 23 patients are treated with Attentalin syrup with a starting dose of 5 cc/day then 10 cc/day after a week, . ADHD RATING SCALE questionnaire will be completed by the psychiatric resident on day zero and in week 3 and 6.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Atiyeh Majidi

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Honarestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Atiyeh Majidi

Position

Psychiatry resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Latest degree

Medical doctor

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available