

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Efficacy of Reboxetin in childhood and adolescence with ADHD and Anxiety disorder in out-patient clinic

Protocol summary

Summary

The aim of the study is to evaluate treatment clinical efficacy of Reboxetine in children and adolescents who have both attention deficit hyperactivity and anxiety disorders. This study was an open-label study in which twenty-five patients of Child and Adolescent Psychiatry Outpatient Clinic were engaged during four weeks. In this period, Reboxetine, 4 mg tablet, was prescribed twice daily. Intensity of hyperactivity and anxiety were measured by using Conners' parent questionnaire and the Hamilton Rating Scale, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905033979N3**
Registration date: **2011-01-31, 1389/11/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-31, 1389/11/11

Registrant information

Name

Forugh Riahi

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

riahi-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Reserch Devision, Ahvaz Jondishapoor Medical University

Expected recruitment start date

2009-02-19, 1387/12/01

Expected recruitment end date

2010-02-20, 1388/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Reboxetin in childhood and adolescence with ADHD and Anxiety disorder in out-patient clinic

Public title

Efficacy of Reboxetin in childhood and adolescence with ADHD and Anxiety disorder in out-patient clinic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ADHD and Anxeity disorder except for OCD and PTSD Exclusion criteria: MR, presence of any medical problems, other psychotic disorder, drug or substance use

Age

From **6 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Devision, Ahvaz Jondishapoor Medical University

Street address

Golestan, Ahvaz

City

Ahvas

Postal code

15794-61357

Approval date

2009-12-20, 1388/09/29

Ethics committee reference number

7782/20/8/p

Health conditions studied**1****Description of health condition studied**

Attention deficit disorder with hyperactivity and anxiety

ICD-10 code

F90, F93

ICD-10 code description**Primary outcomes****1****Description**

Attention deficit hyperactivity disorder

Timepoint

at the beginning (baseline) and the end of second and fourth weeks of the study.

Method of measurement

The Conner's parent rating scale-revised short version [CPRS -R(S)] scores

2**Description**

Anxiety

Timepoint

At the beginning (baseline) and the end of second and fourth weeks of the study.

Method of measurement

The Hamilton anxiety rating scale scores

Secondary outcomes**1****Description**

Rate of diastolic and systolic blood pressure

Timepoint

at the beginning (baseline) and the end of second and fourth weeks of the study.

Method of measurement

Assessment of peripheral blood pressure with blood pressure monitor

2**Description**

Rate of side effects

Timepoint

at the beginning (baseline) and the end of second and fourth weeks of the study.

Method of measurement

based on Pharmaceutical list

3**Description**

Pulse rate

Timepoint

at the beginning (baseline) and the end of second and fourth weeks of the study.

Method of measurement

Assessment of Peripheral pulse rate

Intervention groups**1****Description**

Reboxitine 4 mg tablet twice daily

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Child and Adolecent Psychiatry Clinic, Golestan Hospital

Full name of responsible person

Forugh Riahi

Street address

Psychiatry Group, Golestan Hospital, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Reserch Devision, Ahvaz Jondishapoor Medical University

Full name of responsible person

Makhmal Zade Sharif

Street address

Ahvaz Jondishapoor Medical University, Golestan street

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Reserch Devision, Ahvaz Jondishapoor Medical University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jondishapoor Medical University

Full name of responsible person

Forugh Riahi

Position

Child Psychiatrist, Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Forugh Riahi

Position

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty