

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

pioglitazone added to risperidone in the treatment of Autism: A double blind and placebo controlled trial

Protocol summary

Summary

The objective of this study is to assess the efficacy of Pioglitazone in the treatment of autism. Fifty children between the ages 3 and 12 years with a DSM IV clinical diagnosis of autistic disorder and who will be outpatients from a specialty clinic for children will be recruited. The children should present with a chief complaint of severely disruptive symptoms related to autistic disorder. Patients will be randomly allocated into Pioglitazone (30 mg/day) + Risperidone (1-2mg/day) or Placebo + Risperidone (1-2mg/day) for a 10-week, double-blind, placebo-controlled study. Patients will be assessed at baseline and after 2, 4, 6, 8 and 10 weeks of starting medication. The primary outcome measure is the Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (Irritability subscale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202281556N37**

Registration date: **2012-03-01, 1390/12/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-01, 1390/12/11

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of Medical Sciences

Expected recruitment start date

2012-03-15, 1390/12/25

Expected recruitment end date

2014-03-16, 1392/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

pioglitazone added to risperidone in the treatment of Autism: A double blind and placebo controlled trial

Public title

pioglitazone in the treatment of autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-DSM IV clinical diagnosis of autistic disorder, 2-children between the ages of 3 and 11 years ,3- presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone) Exclusion Criteria:1- Presence of any active medical problem, 2-any diagnosis in Axis I and II except for mental retardation, 3-history of allergy to Amantadine,4- receiving any psychotropic medications during past two weeks prior to the trial, 5- presence of hepatic disease, 6-history of seizure

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshvarz Blvd

City

Tehran

Postal code**Approval date**

2012-02-20, 1390/12/01

Ethics committee reference number

16043

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

Childhood autism

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes**1****Description**

Severity of Autism

Timepoint

Baseline and weeks 2, 4, 6, 8, 10

Method of measurement

Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (irritability subscale)

Secondary outcomes

empty

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

Tablet Pioglitazone 30 mg/day+ Tablet Risperidon 1-2 mg/day as intervention for 10 weeks

Category

Treatment - Drugs

2**Description**

Tablet Risperidone 1-2 mg/day +Capsule Placebo as control for 10 weeks

Category

Placebo

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

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

South Kargar Sreet, Roozbeh Hospital

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

Keshvarz Blvd

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

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**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work**Street address**

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Full name of responsible person

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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