

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

A double- blind placebo controlled trial of Pentoxifylline added to Risperidone in patients with autistic disorders

Protocol summary

Summary

The objective of this study is to assess the efficacy of Pentoxifylline in the treatment of autism. Forty children between the ages 3 and 11 years (inclusive) with a DSM IV clinical diagnosis of autism 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 Pentoxifylline (200- 400 mg/day) + Risperidone (3.5mg/day) or Placebo + Risperidone (3.5mg/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 (total score).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711161556N7**

Registration date: **2009-03-13, 1387/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-03-13, 1387/12/23

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 5541 2222

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2007-04-20, 1386/01/31

Expected recruitment end date

2009-04-20, 1388/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double- blind placebo controlled trial of Pentoxifylline added to Risperidone in patients with autistic disorders

Public title

Pentoxifylline in the treatment of autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: DSM IV clinical diagnosis of autism, children and adolescents between the ages of 3 and 11 years (inclusive), Exclusion Criteria: Presence of any active medical problem, any diagnosis in Axis I and II except for mental retardation, history of allergy to Pentoxifylline, receiving any psychotropic medications during past two weeks prior to the trial, presence of aggressive behavior that needs Risperidone

Age

From **3 years** old to **11 years** old

Gender

Both

Phase

2

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

Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2007-04-20, 1386/01/31

Ethics committee reference number

5401

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

Secondary outcomes

empty

Intervention groups

1

Description

Tablet Pentoxifylline 400 mg/day+ Tablet Risperidon 1-3.5 mg as intervention

Category

Treatment - Drugs

2

Description

Tablet Risperidone 1-3.5 mg/day +Tablet Placebo as control

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Psychiatry Hospital

Full name of responsible person

Dr. Mohhamad Reza Mohhamadi

Street address

Roozbeh Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Foutohi

Street address

Keshavarz Blvd

City

Tehran

Grant name

Grant code / Reference number

5401

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Shahin Akhondzadeh
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