Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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. Fourty 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)

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

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 retatdation, 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 weerks 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

Prof. of Clinical Psychopharmacology, Ph.D.

Other areas of specialty/work

Street address

Roozbeh Hospital

City

Tehran

Postal code

13337

Phone

+98 21 5541 2222

Fax

+98 21 5541 9113

Email

s.akhond@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clonical Psychopharmacology, Ph.D.

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Fax

+98 21 5541 9113

Email

s.akhond@sina.tuma.ac.ir

Web page address

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