

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A double-blind placebo controlled trial of celecoxib added to risperidone in patients with autistic disorder.

Protocol summary

Summary

The Goal of this trial 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 at roozbeh psychiatric Hospital will be recruited. Patients will be randomly allocated to celecoxib + risperidone (Group A) or placebo + risperidone (Group B) for a 10-week. The dose of risperidone was titrated up to 1-3.5 mg/day. The dose of celecoxib was titrated up to 300 mg/day. Patients will be assessed at baseline and after 2, 4, 6, 8 and 10 weeks. The measure of the outcome will be the Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (total score).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711091556N2**

Registration date: **2009-02-12, 1387/11/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2009-02-12, 1387/11/24

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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-02-19, 1387/12/01

Expected recruitment end date

2011-02-19, 1389/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double-blind placebo controlled trial of celecoxib added to risperidone in patients with autistic disorder.

Public title

Celecoxib and Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Ages 3 to 11 years, clinical diagnosis of autism (the diagnosis of autism based on semi structured interview with the parent), lack of use of psychotropic drugs at least two weeks before trial. Exclusion Criteria: Previously received neuroleptics or any psychotropic drug treatment 6 months prior to recruitment or having significant active medical problem; Children with severe or profound mental retardation in whom a definitive diagnosis of autism could not be made; Any diagnosis of psychiatric disorder in Axis I and II; Any organic disorder.

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

Tehran University of Medical sciences, Keshavarz Blv

City

Tehran

Postal code

Approval date

2009-01-23, 1387/11/04

Ethics committee reference number

8144

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes

1

Description

The Aberrant Behavior Checklist (ABC)

Timepoint

every two weeks

Method of measurement

The Aberrant Behavior Checklist (ABC)

2

Description

Childhood Autism Rating Scale

Timepoint

every two weeks

Method of measurement

Childhood Autism Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Risperidone + Celecoxib 300 mg/day

Category

Treatment - Drugs

2

Description

Control: Risperidone + placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Psychiatric Hospital

Full name of responsible person

Prof. M.R. Mohammadi

Street address

Roozbeh Psychiatric Hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. A. Fotouhi

Street address

Tehran University of Medical Sciences, Keshavarz Blv.

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

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
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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