

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Rosiglitazone as an adjuvant therapy to risperidone in children with autism spectrum disorder: a randomized placebo-controlled double-blind clinical trial

Protocol summary

Study aim

Rosiglitazone as an adjuvant therapy in children with autism spectrum disorder

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed on patients attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of autism based on DSM5 and ABC-C. Exclusion criteria: Medically active disease - The presence of another psychological diagnosis in DSM 3 axis - History of previous sensitivity and intolerance to rosiglitazone - History of seizures and liver disorders - Taking antipsychotic drugs such as Risperidone before entering the study - Alanine aminotransferase (ALT) level < 2.5 at the beginning of the study

Intervention groups

Control group: Children with autism received daily risperidone (0.5 mg per day, and 0.5 mg added up to seven days, up to a maximum dose of 3 mg per day) and placebo for 10 weeks. Intervention group: Children with autism receive daily risperidone (0.5 mg per day, and 0.5 mg added up to seven days, up to a maximum dose of 3 mg per day) and rosiglitazone (4 mg in two doses) for 10 weeks.

Main outcome variables

Autism severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N150**
Registration date: **2023-04-24, 1402/02/04**

Registration timing: **prospective**

Last update: **2023-04-24, 1402/02/04**

Update count: **0**

Registration date

2023-04-24, 1402/02/04

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

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2025-06-22, 1404/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Rosiglitazone as an adjuvant therapy to risperidone in children with autism spectrum disorder: a randomized placebo-controlled double-blind clinical trial

Public title

The effect of rosiglitazone in the treatment of autism

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of autism based on DSM5 and ABC-C

Exclusion criteria:

Medically active disease The presence of another psychological diagnosis in DSM 3 axis History of previous sensitivity and intolerance to rosiglitazone History of seizures and liver disorders Taking antipsychotic drugs such as Risperidone before entering the study Alanine aminotransferase (ALT) level < 2.5 at the beginning of the study

Age

From **5 years** old to **11 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of School of Medicine, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-12-21, 1401/09/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.639

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

Autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

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

Severity of irritability

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community (ABC-C)

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

The severity of hyperactivity/noncompliance

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community (ABC-C)

2**Description**

The severity of lethargy/social withdrawal

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community (ABC-C)

3**Description**

The severity of stereotypic behavior

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community (ABC-C)

4**Description**

The severity of inappropriate speech

Timepoint

Baseline and weeks 5, and 10

Method of measurement

By Aberrant Behavior Checklist-Community (ABC-C)

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

Control group: Children with autism received daily risperidone (0.5 mg per day, and 0.5 mg added up to seven days, up to a maximum dose of 3 mg per day) and placebo for 10 weeks.

Category

Placebo

2**Description**

Intervention group: Children with autism receive daily risperidone (0.5 mg per day, and 0.5 mg added up to seven days, up to a maximum dose of 3 mg per day) and rosiglitazone (4 mg in two doses) for 10 weeks.

Category

Treatment - Drugs

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

Roozbeh hospital

Full name of responsible person

Prof. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street

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Tehran

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1333715914

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mohammadimr@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

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Tehran University of Medical Sciences, Keshavarz Blvd.

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afotouhi@tums.ac.ir

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

No

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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کارگر جنوبی بیمارستان روزبه

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tehran University of Medical Sciences

Position

Dr. Shahin Akhondzadeh

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Ph.D.

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Tehran University of Medical Sciences

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2023 to 2028

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Users should cite the resource of data

From where data/document is obtainable

Prof. Shahin Akhondzadeh

What processes are involved for a request to access data/document

By E-mail

Comments