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)
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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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Tehran

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1333715914

Phone

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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

Street address

Tehran University of Medical Sciences, Keshavarz Blvd.

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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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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Dr. Shahin Akhondzadeh

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Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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