Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

L-theanine adjunct to risperidone for irritability of autistic children: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim
Studying the effect of L-theanine with risperidone on irritability in children with autism

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: Age between 5-11 years - Diagnosis of autism spectrum disorder based on DSM-V - Patients who have specific behavioral problems such as aggression, hyperactivity, unusual, and stereotyped behaviors. Exclusion criteria: Previous prominent psychiatric disorders (e.g., depression) - Comorbidities - History of allergy or intolerance to risperidone or L-theanine - History of seizure or liver dysfunction - History of treatment with antipsychotic medications in the past six months

Intervention groups
Control group: Risperidone (Risperdal; Janssen Pharmaceuticals, Beerse, Belgium) started at a dose of 0.5 mg and increased by 0.5 mg per week if there are no side effects (for the first three weeks). The therapeutic range for risperidone will be 2-3.5 mg, with a maximum dose of 2 mg for children weighing less than 30 kg and 3.5 mg per day for children weighing 30 kg or more. Placebo will also be administered once a day for ten weeks. Intervention group: Risperidone (Risperdal; Janssen Pharmaceuticals, Beerse, Belgium) started at a dose of 0.5 mg and increased by 0.5 mg per week if there are no side effects (for the first three weeks). The therapeutic range for risperidone will be 2-3.5 mg, with a maximum dose of 2 mg for children weighing less than 30 kg and 3.5 mg per day for children weighing 30 kg or more. L-Theanine capsule (400 mg) (Institute of Medicinal Plants) will be prescribed once daily for ten weeks.

Main outcome variables
Severity of autism symptoms.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N170**
Registration date: **2026-05-13, 1405/02/23**
Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**
Update count: **0**

Registration date
2026-05-13, 1405/02/23

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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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2028-05-21, 1407/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
L-theanine adjunct to risperidone for irritability of autistic children: A randomized, double-blind, placebo-controlled trial

Public title
L-theanine adjunct to risperidone in autism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 5-11 years Diagnosis of autism spectrum disorder based on DSM-V Patients who have specific behavioral problems such as aggression, hyperactivity, unusual, and stereotyped behaviors
Exclusion criteria:
Previous prominent psychiatric disorders (e.g., depression) Comorbidities History of allergy or intolerance to risperidone or L-theanine History of seizure or liver dysfunction History of treatment with antipsychotic medications in the past six months
Age
From **5 years** old to **11 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

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, Pour Sina St., Qods St., Enghelab St.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2026-01-27, 1404/11/07
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1405.111

Health conditions studied

1

Description of health condition studied
Autism spectrum disorder
ICD-10 code
F84.0
ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Irritability
Timepoint
Beginning of the study and weeks 0 - 5 - 10
Method of measurement
By Aberrant Behavior Checklist-Community (ABC-C)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Risperidone (Risperdal; Janssen Pharmaceuticals, Beerse, Belgium) started at a dose of 0.5 mg and increased by 0.5 mg per week if there are no

side effects (for the first three weeks). The therapeutic range for risperidone will be 2-3.5 mg, with a maximum dose of 2 mg for children weighing less than 30 kg and 3.5 mg per day for children weighing 30 kg or more. Placebo will also be administered once a day for ten weeks.

Category

Placebo

2

Description

Intervention group: Risperidone (Risperdal; Janssen Pharmaceuticals, Beerse, Belgium) started at a dose of 0.5 mg and increased by 0.5 mg per week if there are no side effects (for the first three weeks). The therapeutic range for risperidone will be 2-3.5 mg, with a maximum dose of 2 mg for children weighing less than 30 kg and 3.5 mg per day for children weighing 30 kg or more. L-Theanine capsule (400 mg) (Institute of Medicinal Plants) will be prescribed once daily for ten 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

City
Tehran

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Tehran

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1333715914

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+98 21 5541 2222

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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. Ramin Kordi

Street address
Tehran University of Medical Sciences, Keshavarz Blvd.

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1417653761

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vcr@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

Street address
Roozbeh Hospital, South Kargar Street

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Tehran

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Tehran

Postal code
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Email
s.akhond@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Shahin Akhondzadeh

Position
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Shahin Akhondzadeh

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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 2026 to 2030

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