Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Resveratrol add on therapy to risperidone in irritibility of children with autism: a randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim
The objective of this study is to assess the efficacy of Resveratrol in the treatment of autism

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be conducted among children with autistic disorder attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: DSM-5 clinical diagnosis of autistic disorder children between the ages of 3 and 12 years presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone) Exlusion criteria:Presence of any active medical problem other psychiatric diagnosis except for mild to moderate Intellectual disability receiving any antipsychotic medications during past monthprior to the trial severe hepatic disease history of allergy to risperidone and intolerance of it History of seizure requiring change of antiepileptic dose during the last month seizure during the last 6 months

Intervention groups
The participants will be randomly allocated into two groups. Intervention group(25 persons) will receiveResveratrol (500 mg/day) and risperidone (1 to 3.5 mg per day) and control group(25 persons) will receive risperidone(1 to 3.5 mg per day) for 12 weeks.

Main outcome variables
severity of autism

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N104**
Registration date: **2017-12-25, 1396/10/04**
Registration timing: **prospective**
Last update: **2017-12-25, 1396/10/04**
Update count: **0**

Registration date
2017-12-25, 1396/10/04

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
2018-01-08, 1396/10/18

Expected recruitment end date
2020-01-08, 1398/10/18

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Resveratrol add on therapy to risperidone in irritibility of children with autism: a randomized double-blind placebo-controlled clinical trial

Public title
Resveratrol in treatment of autism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

DSM-5 clinical diagnosis of autistic disorder children between the ages of 3 and 12 years presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone)

Exclusion criteria:

Presence of any active medical problem other psychiatric diagnosis except for mild to moderate Intellectual disability receiving any antipsychotic medications during past monthprior to the trial severe hepatic disease history of allergy to risperidone and intolerance of it History of seizure requiring change of antiepileptic dose during the last month seizure during the last 6 months

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permuted block

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, clinicians and outcome raters will be blind regarding grouping

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-01-08, 1396/10/18

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4173

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 autism

Timepoint

Baseline and weeks 4, 8 and 12

Method of measurement

By Aberrant Behavior Checklist-Community(ABC-C) and Childhood Autism Rating scale(CARS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet Resveratrol(500 mg per day) plus Risperidone (1 to 3.5 mg per day) for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Tablet placebo plus Risperidone(1 to 3.5 mg per day) for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Hospital

Full name of responsible person

Prof. M.R. Mohammadi

Street address

Roozbeh Hospital
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1333715914
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
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msahrai@tums.ac.ir
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
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
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
Latest degree
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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

No - There is not 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 2020 to 2025

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

En by citing the resourse

From where data/document is obtainable

Professor Shahin Akhondzadeh

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

by e mail

Comments