Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Simvastatin added to risperidone in the treatment of Autism: a double blind and placebo controlled trial

Protocol summary

Summary

The objective of this study is to assess the efficacy ofSimvastatin in the treatment of autism. 40 children between the ages 4 and 12 years with a DSM-5 clinical diagnosis of autistic disorder and who will be outpatients from a specialty clinic for children will be recruited. The children should present with a chief complaint of severely disruptive symptoms related to autistic disorder. Patients will be randomly allocated into simvastatin (20 mg/day for children below 10 years old and 40 mg/day for children older than 10) + Risperidone (1-3.5mg/day) or Placebo + Risperidone (1-3.5mg/day) for a 10-week, double-blind, placebo-controlled study. Patients will be assessed at baseline and after 5 and 10 weeks of starting medication. The primary outcome measure is the Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (Irritability subscale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602041556N86**
Registration date: **2016-02-04, 1394/11/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-02-04, 1394/11/15

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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+98 21 5541 2222

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Simvastatin added to risperidone in the treatment of Autism: a double blind and placebo controlled trial

Public title

Simvastatin in the treatment of Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: DSM-5 clinical diagnosis of autistic disorder; children between the ages of 4 and 12 years old; presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone). Exclusion criteria: presence of any active medical problem; any other psychiatric diagnosis except for mild mental retardation; receiving any psychotropic medications during past two weeks prior to the trial; presence of hepatic disease; history of seizure; history of allergy to simvastatin or intolerance of it; neutropenia, anemia or thrombocytopenia and renal

disease.

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
N/A

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
Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Ghods St., Keshvarz Blvd.

City
Tehran

Postal code

Approval date
2015-12-22, 1394/10/01

Ethics committee reference number
IR.TUMS.REC.1394.1602

Health conditions studied

1

Description of health condition studied
Autistic Disorder

ICD-10 code
F84.0

ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Severity of Autism

Timepoint
Baseline and weeks 5 and 10 after beginning of treatment

Method of measurement
Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (Irritability subscale)

Secondary outcomes

empty

Intervention groups

1

Description
Tablet simvastatin 20 to 40 mg/day+ Tablet Risperidon 1-3.5 mg/day as intervention 10 for 10 weeks

Category
Treatment - Drugs

2

Description
Tablet Risperidone 1-3.5 mg/day + Placebo as control for 10 weeks

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh Hospital

Full name of responsible person
Dr. Shahin Akhondzadeh

Street address
Roozbeh Hospital; South Kargar Sreeet

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Masoud Yunesian

Street address
Tehran University of Medical Sciences, Ghods St., Keshvarz Blvd

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
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Prof. Shahin Akhondzadeh
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Other areas of specialty/work
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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