Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Assessment the efficacy of atomoxetin(stramox) in autism spectrum disorders 6-17 years old

Protocol summary

Summary
(1) Objectives: Assessment the efficacy of Atomoxetin (Stramox) in autism spectrum disorders 6-17 years old. (2) Design: Results of the study will be assessed by CARS, CGI questionnaire and check list of drugs side effects. (3) Setting and conduct: The samples were randomly divided into two groups of 20 persons. Patients at weeks zero, four, eight in terms of therapeutic effects and adverse drug reactions are evaluated. (4) Participants including major eligibility criteria: Eligible patients after gaining the consent of a parent or legal guardian patients will be enrolled. Patients who had organic disease, patients have been treated with other psychotropic drugs and also patients with other psychiatric disorders are excluded. (5) Intervention: Both groups were treated with Risperidone prior to entering the study, first group is treated with placebo and the second group is treated with Atomoxetine. (6) Main outcome measures (variables): Autism

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2016022826802N1**
Registration date: **2016-08-31, 1395/06/10**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2016-08-31, 1395/06/10

Registrant information
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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research of mashhad university of medical sciences

Expected recruitment start date
2015-08-23, 1394/06/01
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
Assessment the efficacy of atomoxetin(stramox) in autism spectrum disorders 6-17 years old

Public title
Assessment the efficacy of atomoxetin(stramox) in autism spectrum disorders
Purpose
Treatment
Inclusion/Exclusion criteria
The inclusion criteria: Of all patients with ASD, ranging in age from 6 to 17 years; Parent's Consent; No obvious organic disease; The lack of other psychiatric disorders; Not taking other psychoactive medications other than risperidone; IQ higher than 50 on the basis of Weiland test The exclusion criteria: In the absence of cooperation of parents after inclusion; the risk of any side effect or another disease that cause a problem in results.

Age
From **6 years** old to **17 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of mashhad university of medical science
Street address
Qoreishi Building, Daneshgah St., Mashhad, Iran.
City
Mashhad
Postal code
Approval date
2015-08-23, 1394/06/01
Ethics committee reference number
IR.MUMS.REC.1394.95

Health conditions studied

1

Description of health condition studied
Autism spectrum disorders
ICD-10 code
F84.0, F84
ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Autism
Timepoint
Previous the syudy, 4 weeks after study, 8 weeks after study.
Method of measurement
CARS test,CGI test

Secondary outcomes

1

Description
Drug's side effect
Timepoint
Previous the study, 4weeks after study, 8 weeks after study
Method of measurement
Check list

Intervention groups

1

Description
The intervention group have been treated with risperidone is also treated with atomoxetine. Dosing and titration of the drug individually, but the total dose of atomoxetine is 0.5 mg per kg at the start and every five days on body weight and medical condition and the patient's tolerance increases and maximum doses of 1.2 mg per kg, the duration of intervention is 8 weeks.
Category
Treatment - Drugs

2

Description
The intervention group have been treated with risperidone is also treated with placebo. The duration of intervention is 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Outpatient Clinic
Full name of responsible person
Mahbube Eslamzadeh
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Ibne Sina Hospital, Amel Blvd.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of mashhad university of medical sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of mashhad 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

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Person responsible for scientific inquiries

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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