

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

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

Protocol summary

Summary

(1) Objectives: Assessment the efficacy of Atomoxetine (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

Name

Mahbubeh Eslamzadeh

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2701

Email address

eslamzadehm921@mums.ac.ir

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 atomoxetine(stramox) in autism spectrum disorders 6-17 years old

Public title

Assessment the efficacy of atomoxetine(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

Street address

Ibne Sina Hospital, Amel Blvd.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of mashhad university of medical sciences

Full name of responsible person

Dr Mahyar Mirheydari

Street address

Qoreishi Building, Daneshgah St., Mashhad, Iran.

City

Mashhad

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**Contact****Name of organization / entity**

Mashhad University of Medical sciences

Full name of responsible person

Dr Mahbubeh Eslamzadeh

Position

Psychiatric Resident

Other areas of specialty/work**Street address**

Ibn e Sina Hospital, Bu-Ali Sq, Amel Blvd, Mashhad, Iran.

City

Mashhad

Postal code**Phone**

+98 51 3711 2721

Fax**Email**

eslamzadehm921@mums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Paria Hebrani

Position

Associate Professor

Other areas of specialty/work**Street address**

Ibn e sina Hospital, Bu-Ali Sq, Amel Blvd, Mashhad, Iran.

City

Mashhad

Postal code

IRAN

Phone

+98 51 3711 2722

Fax

+98 51 3711 2701

Email

hebranip@mums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahbubeh Eslamzadeh

Position

Psychiatric Resident

Other areas of specialty/work**Street address**

Ibn e Sina Hospital, Bu-Ali Sq, Amel Blvd, Mashhad, Iran.

City

Mashhad

Postal code**Phone**

+98 51 3608 4315

Fax**Email**

Eslamzadehm921@mums.ac.ir;

mahbub_1384m@yahoo.com

Web page address**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