

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

A comparative study on the effectiveness of Risperidone versus Risperidone plus naltrexone in treatment of autistic spectrum disorder in children with 6-12 years old

Protocol summary

Summary

The goal of study is comparison between Risperidon & Risperidon plus naltrexone in treatment of autistic children with 4-12 years old. The study is a cross over clinical trial that is performed double blindly on 30 patients that refer to Ibn-e-sina hospital. Inclusion criteria are age between 4-12 years old and autistic spectrum disorder and exclusion criterion is having severe medical disorders. CARS questionnaire is filled before treatment, then patients are randomly divided to two groups; one group takes risperidone alone & another group takes risperidone + naltrexone for 8 weeks. CARS are filled in weeks 0, 4, 8 to follow symptoms. During 2 weeks of washout period, each 2 group take risperidone only and fill CARS, after that naltrexone is added to the first group and risperidone is continued for second group. CARS is filled after crossover in weeks 4, 8. Finally the result of CARS will be compared between 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108155280N5**

Registration date: **2013-02-10, 1391/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-10, 1391/11/22

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina

Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

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nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2011-09-11, 1390/06/20

Expected recruitment end date

2013-06-10, 1392/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effectiveness of Risperidone versus Risperidone plus naltrexone in treatment of autistic spectrum disorder in children with 6-12 years old

Public title

A comparative study on the effectiveness of Risperidone versus Risperidone plus naltrexone in treatment of autistic spectrum disorder in children with 6-12 years old

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- children with 4-12 years old; 2- children with at least one of the autistic spectrum disorder signs; 3- Fill out informative consent sheet in order to include the study. Exclusion criteria: 1- Children

with severe medical disorders; 2- The history of severe drug sensitivity to naltrexone or risperidone.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2011-04-30, 1390/02/10

Ethics committee reference number

89548

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

autism

Timepoint

weeks 0,4,8,10,14,18

Method of measurement

CARS

Secondary outcomes

empty

Intervention groups

1

Description

0.5 to 2mg per day risperidone tablet for 18 week.

Category

Treatment - Drugs

2

Description

naltrexone capsule (25mg) in dosage of 0.5 to 1.5 mg per kg per day for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

specialty clinic for children at Ibn-e-Sina psychiatric Hospital

Full name of responsible person

Dr fatemeh Moharrari

Street address

City

Mashhad

2

Recruitment center

Name of recruitment center

specialty clinic for children at Dr Sheykh hospital

Full name of responsible person

Dr Ebrahim Abdollahian

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Marjan Ardakanian

Street address

Daneshgah Street, Ghoreishi Building

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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, Ibn-e-sina hospital

Full name of responsible person

Dr Fatemeh Moharari

Position

Assistant Professor, Child and Adolescent Psychiatrist, Head of Ibn-e-Sina Hospital & Hejazi Hosoiita

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

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mohararif1@mums.ac.ir

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

Ibn-e-Sina psychiatric Hospital, Mashhad university of medical sciences

Full name of responsible person

Dr Ebrahim Abdollahian

Position

Psychiatry specialist of child and adolescent

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

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

Ibn-e-Sina Hospital, Mashhad University of Medical Sciences

Full name of responsible person

Dr Azam Hoseini

Position

resident of psychiatry

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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*