# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 May 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 fallow 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

**Email address**

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 Scinces

**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 Scinces
**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 scinces, 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 Hosoita
**Other areas of specialty/work**
**Street address**
Ibn-e-Sina psychiatric Hospital, Horre ameli avenue, Boo-Ali square
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**Postal code**
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+98 51 1711 2701
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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**
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## 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
**Other areas of specialty/work**
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hoseinia871@mums.ac.ir
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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*