

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### minocycline 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 of Minicycline in the treatment of autism. 40 children between the ages 3 and 12 years with a DSM IV 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 Minocycline (100 mg/day ) + Risperidone (1-2mg/day) or Placebo + Risperidone (1-2mg/day) for a 10-week, double-blind, placebo-controlled study. Patients will be assessed at baseline and after 2, 4, 6, 8 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: **IRCT201302201556N50**

Registration date: **2013-02-21, 1391/12/03**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2013-02-21, 1391/12/03

##### Registrant information

##### Name

Shahin Akhondzadeh

##### Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5541 2222

##### Email address

s.akhond@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2013-03-21, 1392/01/01

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

minocycline added to risperidone in the treatment of Autism: A double blind and placebo controlled trial

##### Public title

Minocycline in the treatment of autism

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: 1-DSM IV clinical diagnosis of autistic disorder, 2-children between the ages of 3 and 12 years ,3- presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone) Exclusion Criteria:1- Presence of any active medical problem, 2-any diagnosis in Axis I and II except for mental retardation, 3- receiving any psychotropic medications during past two weeks prior to the trial, 4-presence of hepatic disease, 5-history of seizure

##### Age

From **3 years** old to **12 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)**

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**

Keshvarz Blvd

**City**

Tehran

**Postal code****Approval date**

2013-02-18, 1391/11/30

**Ethics committee reference number**

20288

**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 2, 4, 6, 8, 10

**Method of measurement**

Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (irritability subscale)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Capsule Minocycline 100 mg/day+ Tablet Risperidon 1-2 mg/day as intervention 10 for 10 weeks

**Category**

Treatment - Drugs

**2****Description**

Tablet Risperidone 1-2 mg/day +Capsule 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**

South Kargar Sreet, Roozbeh Hospital

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Akbar Fotouhi

**Street address**

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*

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Prof. Shahin Akhondzadeh  
**Position**  
Prof. of Clinical Psychopharmacology  
**Other areas of specialty/work**  
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South Kargar street; Roozbeh Hospital  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*