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 (Irritibility 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)
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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 weerks 2, 4, 6, 8, 10
Method of measurement
Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (irritibility 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 Sreeet, 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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Prof. Shahin Akhondzadeh
Position
Prof. of Clinical Psychopharmacology
Other areas of specialty/work
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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