

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

A double - blind placebo controlled trial of Ginkgo Biloba added to risperidone in patint with autistic disorder

Protocol summary

Summary

The objective of this study is to assess the efficacy of Ginkgo biloba in the treatment of autism. Fourty children between the ages 3 and 12 years with a DSM IV clinical diagnosis of autism and who will be outpatients 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 Ginkgo biloba (80- 120 mg/day) + Risperidone (3.5mg/day) or Placebo + Risperidone (3.5mg/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 (total score).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012031556N19**

Registration date: **2010-12-04, 1389/09/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-04, 1389/09/13

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

1- Tehran University of Medical Sciences 2- Kurdistan University of Medical Sciences-Sanandaj-Iran

Expected recruitment start date

2010-04-06, 1389/01/17

Expected recruitment end date

2011-10-06, 1390/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double - blind placebo controlled trial of Ginkgo Biloba added to risperidone in patint with autistic disorder

Public title

Ginkgo biloba in the treatment of autistic disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: DSM IV clinical diagnosis of autism, children and adolescents between the ages of 3 and 12 years (inclusive), Exclusion Criteria: Presence of any active medical problem, any diagnosis in Axis I and II except for mental retatdation, history of allergy to Ginkgo Biloba, receiving any psychotropic medications during past two weeks prior to the trial

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

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2010-03-06, 1388/12/15

Ethics committee reference number

9500

Health conditions studied

1

Description of health condition studied

Childhood autism

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

Secondary outcomes

empty

Intervention groups

1

Description

Tablet Ginkgo biloba 80-120 mg/day+ Tablet Risperidon 1-3.5 mg as intervention

Category

Treatment - Drugs

2

Description

Tablet Risperidone 1-3.5 mg/day +Tablet Placebo as control

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roazbeh Hospital

Full name of responsible person

Dr. Mohhamad Reza Mohhamadi

Street address

south kargar street

City

Tehran

2

Recruitment center

Name of recruitment center

Qhods Hospital- Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Farzin Rezaei

Street address

Pasdaran Blvd- Qhods hospital - Sanandaj

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Keshavarz 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
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

2

Sponsor
Name of organization / entity
 Kurdistan University of Medical Sciences
Full name of responsible person
 Dr Ataollah Heydari
Street address
 Pasdaran Blvd-Kurdistan university of Medical Sciences-Deputy of research- Sanandaj
City
 Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Kurdistan University of Medical Sciences
Proportion provided by this source
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

Person responsible for scientific 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
Street address
 Roozbeh Hospital-South Karegar street
City
 Tehran
Postal code
Phone
 +98 21 5541 2222
Fax
 +98 21 5541 9113
Email
 s.akhond@sina.tums.ac.ir
Web page address

Person responsible for updating data

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
Street address
 Roozbeh Hospital
City
 Tehran
Postal code
 13337
Phone
 +98 21 5541 2222
Fax
 +98 21 5541 9113
Email
 s.akhond@sina.tums.ac.ir
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