Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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 weerks 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
Roozbeh 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
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Person responsible for updating data

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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