Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Galantamine 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 Galantamine in the treatment of autism. Fifty 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 Galantamine (2-24 mg/day) + Risperidone (1-2mg/day) or Placebo + Risperidone (1-2mg/day) for a 10-week, double-blind, placebo-controlled study. The initial dose of Galantamine will be 2 mg per day and after one week the dose will be increased to 4 mg twice daily .If tolerated, the dose will be gradually increased to 24 mg per day. Patients will be assessed at baseline and after 5 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: **IRCT201204081556N40**
Registration date: **2012-04-14, 1391/01/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-14, 1391/01/26

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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Galantamine 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-history of allergy to Galantamine,4- receiving any psychotropic medications during past two weeks prior to the trial, 5-

presence of hepatic disease, 6-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: **50**

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
2011-12-22, 1390/10/01

Ethics committee reference number
13216

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 5 and 10 after begining of treatment

Method of measurement
Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (Irritability subscale)

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Galantamine 2-24 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
Dr Ataollah Heydari

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

Full name of responsible person
Prof. Shahin Akhondzadeh

Position
Prof. of Clinical Psychopharmacology

Other areas of specialty/work

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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