

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Riluzole 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 Riluzole 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 Riluzole (50-100 mg/day) + Risperidone (1-3mg/day) or Placebo + Risperidone (1-3 mg/day) for a 10-week, double-blind, placebo-controlled study. Patients will be assessed at baseline and after 5,10 weeks of starting medication. The primary outcome measure is the Aberrant Behavior Checklist-Community (ABC-C) Rating Scale and CGI

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107281556N27**

Registration date: **2011-07-30, 1390/05/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-07-30, 1390/05/08

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

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-23, 1391/07/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Riluzole 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 Riluzole,4- receiving any psychotropic medications during past six 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: 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

Tehran University of Medical Sciences

Street address

Keshavarz Blvd

City

Tehran

Postal code

Approval date

2011-07-17, 1390/04/26

Ethics committee reference number

14009

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 the beginning of the treatment

Method of measurement

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

2

Description

Clinical Global Impression

Timepoint

Baseline and weeks 5, and 10 after the beginning of the treatment

Method of measurement

CGI

Secondary outcomes

empty

Intervention groups

1

Description

Tablet Riluzole 50-100 mg/day+ Tablet Risperidon 1-3 mg/day as intervention 10 for 10 weeks

Category

Treatment - Drugs

2

Description

Tablet Risperidone 1-3 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. Mohhamad Reza Mohhamadi

Street address

south kargar street

City

Tehran

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
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

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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Roozbeh Hospital-South Karegar street

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Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Prof. Shahin Akhondzadeh

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Prof. of Clinical Psychopharmacology

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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