Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Baclofen as adjunctive treatment of Autism: A double blind and placebo controlled trial

Protocol summary

Summary

The objective of this study is to assess the efficacy of Baclofen in the treatment of autism. Forty children between the ages 3 and 12 years with a DSM -5 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 Baclofen (0.6mg/kg/day in three divided doses) + Risperidone (1-3.5mg/day) or Placebo + Risperidone (1-3.5mg/day) for a 10-week, double-blind, placebo-controlled study. 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 (Irritibilityy subscale) and Childhood autism rating scale(CARS) .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701131556N95**
Registration date: **2017-01-13, 1395/10/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-01-13, 1395/10/24

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

2017-01-20, 1395/11/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Baclofen as adjunctive treatment of Autism: A double blind and placebo controlled trial

Public title

Baclofen in the treatment of Autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-DSM 5 clinical diagnosis of autistic disorder; 2-children between the ages of 3 and 11 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 other psychiatric diagnosis except for Intellectual disability; 3-history of allergy to Baclofen; 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
N/A
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
Tehran University of Medical Sciences, Keshvarz Blvd.
City
Tehran
Postal code
Approval date
2016-12-27, 1395/10/07
Ethics committee reference number
IR.TUMS.VCR.REC.1395.1255

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 5 and 10
Method of measurement
Aberrant Behavior Checklist-Community (ABC-C) Rating Scale (irritibility subscale) and Childhood autism rating scale(CARS)

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Baclofen 0.6 mg/kg/day in three divided doses+ Tablet Risperidon 1-3.5 mg/day as intervention for 10 weeks
Category
Treatment - Drugs

2

Description
Tablet Risperidone 1-3.5 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
Roozbeh Hospital, South Kargar Sreeet
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Masoud Yunesian
Street address
Tehran University of Medical Sciences, 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
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Person responsible for updating data

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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