Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Effect of propentofylline add on therapy to risperidon in children with autism: a randomized double-blind placebo-controlled clinical trial

Protocol summary

Study aim
The objective of this study is to assess the efficacy of of propentofylline in the treatment of autism
Design
Randomized double blind and placebo-controlled clinical trial
Settings and conduct
The study will be conducted among children with autistic disorder attending Roozbeh Hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria: DSM-5 clinical diagnosis of autistic disorder children between the ages of4 and 11 years old; presence of behavioral problems such as aggression, overactivity or repetitive behaviors (indication of treatment with risperidone). Exlusion criteria: presence of any active medical problem other psychiatric diagnosis except for mild to moderate Intellectual disability receiving any psychotropic medications except for risperidone during past two weeks prior to the trial severe hepatic disease history of allergy to risperidone and intolerance of it; history of seizure requiring change of antiepileptic dose during the last month seizure during the last 6 months.
Intervention groups
The participants will be randomly allocated into two groups. Intervention group(25 persons) will receive propentofylline (300 BID) and risperidone (1 to 3.5 mg per day) and control group(25 persons) will receive risperidone(1 to 3.5 mg per day) for 12 weeks.
Main outcome variables
Severity of autism

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090117001556N113**
Registration date: **2018-11-15, 1397/08/24**
Registration timing: **prospective**

Last update: **2018-11-15, 1397/08/24**
Update count: **0**
Registration date
2018-11-15, 1397/08/24

Registrant information
Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-11-22, 1397/09/01
Expected recruitment end date
2021-03-21, 1400/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of propentofylline add on therapy to risperidon in children with autism: a randomized double-blind placebo-controlled clinical trial

Public title

Effect of propentofylline in children with autism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

DSM-5 clinical diagnosis of autistic disorder Children between the ages of 4 and 11 years old score 12 or more inirritability subscale of ABC-C

Exclusion criteria:

Presence of any active medical problem Receiving any psychotropic medications except for risperidone during 2 weeks prior to the trial Severe hepatic disease History of allergy to risperidone and intolerance of it History of seizure requiring change of antiepileptic dose during the last month Seizure during the last 6 months

Age

From **4 years** old to **11 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random permuted block

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, clinicians and outcome raters will be blind regarding grouping

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

Province

Tehran

Postal code

1417653761

Approval date

2018-10-23, 1397/08/01

Ethics committee reference number

IR.TUMS.VCR.REC.1397.520

Health conditions studied

1

Description of health condition studied

Autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Severity of autism

Timepoint

Baseline and weeks 4, 8 and 12

Method of measurement

By Aberrant Behavior Checklist-Community(ABC-C) and Childhood Autism Rating scale(CARS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: intervention group: Cap. of propentofylline (300 mg BID) plus Risperidone (1 to 3.5 mg per day) for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Control group: tablet placebo plus Risperidone(1 to 3.5 mg per day) for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Prof. M.R. Mohammadi
Street address
Roozbeh Hospital, South Kargar Street,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
Position
Professor of clinical psychopharmacology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data will be distributed through final report
When the data will become available and for how long
from 2022 to 2027
To whom data/document is available
academic researchers
Under which criteria data/document could be used
En All users should cite the source of data
From where data/document is obtainable
prof Shahin Akhondzadeh
What processes are involved for a request to access data/document
by E mail
Comments