Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Interventional comparison of the effect of cinnarizine with placebo on mood swings and self-harm and stereotyped behaviors of autistic patients

Protocol summary

Study aim
Determining the effect of cinnarizine in control of behavioral symptoms in children with autism
Design
Double-blind randomized clinical trial
Settings and conduct
Children's medical center 34 Children between the ages of 2 and 7 who have been diagnosed with autism by a psychiatrist are enrolled. First, the Behavioral Problems List Questionnaire for people with intellectual disabilities, is completed by the patient's parents or his/her legal guardian. thereafter, patients are divided randomly into 2 groups of 17 people. Cinnarizine or placebo is randomly assigned to each group and patients take it for 3 months (Researcher and also parents don't know the patient belongs to which group). After 3 months, the same questionnaire is filled out again. Finally, patient's scores from the questionnaires are compared to each other and the results are interpreted.
Participants/Inclusion and exclusion criteria
Childeren with 2-7 y.o. Diagnosed with Autism based on DSM-5 criteria
Intervention groups
Receiving Cinnarizine 10-15 mg/kg once daily for 3 months
Main outcome variables
Patient's score from the Behavioral problems questionnaire for people with intellectual disabilities

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110628006907N16**
Registration date: **2022-01-07, 1400/10/17**
Registration timing: **prospective**
Last update: **2022-01-07, 1400/10/17**
Update count: **0**
Registration date
2022-01-07, 1400/10/17

Registrant information
Name
Mahmoudreza Ashrafi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-20, 1400/10/30
Expected recruitment end date
2022-07-22, 1401/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Interventional comparison of the effect of cinnarizine with placebo on mood swings and self-harm and stereotyped behaviors of autistic patients

Public title
The effect of Cinnarizine on Autism
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 2-7 years old Diagnosed with Autism based on DSM5 criteria which is approved by a psychiatrist

Exclusion criteria:

Conditions other than Autism justifying the symptoms of patient

Age

From **2 years** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual simple randomization 34 3-letter codes are generated using www.randomcodegenerator and then half of these codes is assigned to "intervention group" and the other half to "control group". Cinarrizine or placebo (pills are completely identical) are put into identical pockets based on the codes tagged on them. Then the pockets are mixed up. Each patient will recieve a pocket with a code on it which neither researcher or patient don't know whether it belongs to intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

first, 34 3-letter codes will be randomly generated. Each code will be randomly assigned to either control or intervention group. Cinnarizine or placebo pills are put into completely identical pockets and 3-letter codes are written on them. pockets will be mix up. patients or researcher won't know the whether the pocket contains cinnarizine or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address

Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St.

City

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Province

Tehran

Postal code

1417653761

Approval date

2021-12-26, 1400/10/05

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1138

Health conditions studied

1

Description of health condition studied

autism spectrum disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes

1

Description

Patient's score from the Behavioral problems questionnaire for people with intellectual disabilities

Timepoint

at the beginning of trial and 3 months later

Method of measurement

Behavioral problems questionnaire for people with intellectual disabilities

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (17 patients): Receiving Cinnarizine 10-15 mg/kg once daily for 3 months

Category

Treatment - Drugs

2

Description

Control group (17 patients): Receiving placebo 10-15 mg/kg once daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Children's Medical Center
Full name of responsible person
Roya Haghighi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mahmoudreza Ashrafi
Position
Professor of pediatric neurology
Latest degree
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected data about primary and secondary outcomes
When the data will become available and for how long
After the publication of the paper
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Data can be used if the authors' names were mentioned
From where data/document is obtainable
Email
What processes are involved for a request to access data/document
After receiving the request we will consult with all authors and the data can be shared in a week
Comments