

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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

Children 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

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6612 9252

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ashrafim@tums.ac.ir

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". Cinnarizine 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 receive 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.

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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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Gharib

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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keshavarz

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-

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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

Subspecialist

Other areas of specialty/work

Pediatrics

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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