Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Evaluating the effect of adding Curcumin to Risperidone regimen on symptoms of autism spectrum disorder in children

Protocol summary

Study aim
Evaluating the antioxidant effects of Curcumin on symptom severity of Autism spectrum disorder in children.

Design
Clinical trial with two parallel group including main drug group and control group, double blind and randomised recruited during fall and winter of 2019.

Settings and conduct
Autism patients referred to pediatric psychiatric clinics of Dr. Sheikh and Ibn Sina Hospital are included in the research plan after obtaining patient consent. Based on online random number generation program , they are divided into two intervention and control groups. The evaluator and the patient are not aware of the prescription drug

Participants/Inclusion and exclusion criteria
Inclusion criteria: 3 to 12 years old children with autism spectrum disorder under treatment with risperidone for at least 4 weeks. Exclusion criteria: moderate or severe intellectual disability, any known organic medical disease and the need to administer any further drug other than risperidone.

Intervention groups
curcumin group: children under the treatment with risperidone for at least 4 weeks with addition of 40 mgr curcumin daily for further 6 consecutive weeks. placebo group: children under the treatment with risperidone for at least 4 weeks with addition of placebo drug for another 6 more weeks.

Main outcome variables
Assessment of the basic elements of autism symptoms using the questionnaires of measurement childhood Autism rating scale(CARS) and clinical global scale(CGI) At baseline, week 3 and week 6 after drug-placebo initiation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190915044774N1**
Registration date: **2020-04-11, 1399/01/23**
Registration timing: **retrospective**

Last update: **2020-04-11, 1399/01/23**
Update count: **0**

Registration date
2020-04-11, 1399/01/23

Registrant information
Name
Amirfaraz Rezayeezadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-12-11, 1398/09/20
Expected recruitment end date
2020-02-20, 1398/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluating the effect of adding Curcumin to Risperidone regimen on symptoms of autism spectrum disorder in children

Public title
The effect of Curcumin on autism spectrum disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with Autism spectrum disorder Age between 3 to 12 Under Risperidone treatment for at least 1 month
Exclusion criteria:
Other medical or congenital disease Intellectual disability:moderate or severe Without documented consent of the parents
Age
From **3 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who met the inclusion and exclusion criteria were randomly divided into two groups of medication and placebo by online generating random numbers. In the random numbers program, the numbers range was set from 1 to 40, and by choosing no duplicates, we request the production of two sets of random numbers, which are assigned to each group according to visit number of the people.This allocation is concealed from researchers and patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double blind: the form of drug and placebo is the same, and the evaluator, the patient and the analyst are not aware of what treatment they are using, and drug intervention is identified by the pharmacist in sealed envelopes with a numeric code
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad university of medical sciences
Street address
Ghoreishi department, Daneshgah ave, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9175845643
Approval date
2019-05-06, 1398/02/16
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.092

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorders
ICD-10 code
F.84
ICD-10 code description
Autism Spectrum Disorders

Primary outcomes

1

Description
Score in childhood autism rating scale questionnaire (CARS)
Timepoint
Time 0, 3 weeks and 6 weeks after treatment
Method of measurement
Childhood Autism Rating Scale

2

Description
Score in clinical global improvement questionnaire (CGI)
Timepoint
Time 0, 3 weeks and 6 weeks after treatment
Method of measurement
Clinical global improvement score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 120 mg tablet of curcumin orally administered divided into three doses daily for 6 weeks. The tablet is made by the Faculty of Pharmacy of Mashhad University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group: placebo tablets similar to curcumin orally administered divided into three doses daily for 6 weeks. The placebo tablet is made by the Faculty of Pharmacy of Mashhad University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne-sina hospital

Full name of responsible person

Paria Hebrani

Street address

Ebne-sina research center, Horre ameli street, Mashhad

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hebranip@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amirfaraz Rezayeezadeh

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The total individual participants' data and the results of the study after the deidentification of the individuals are shared

When the data will become available and for how long
starting in April 2020

To whom data/document is available
All researchers are able to access the study results

Under which criteria data/document could be used
Unidentifiable information is not shared with another organization

From where data/document is obtainable
Unidentifiable information is not available to applicants

What processes are involved for a request to access data/document
Study data is published in the course of the paper and no other personal data is available to applicants

Comments