

# Exploring curcumin's role in easing irritability in kids with autism

<b>Submission date</b> 20/11/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 23/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 23/11/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Curcumin is a compound found in turmeric, a spice often used in traditional medicine. Some studies have suggested that curcumin may have potential therapeutic effects due to its anti-inflammatory and antioxidant properties. Inflammation and oxidative stress have been implicated in various neurological disorders, including autism. However, it's crucial to note that the research in this area is still emerging, and more robust clinical trials are needed to establish the effectiveness and safety of curcumin for treating autism. The aim of this study is to assess the efficacy of curcumin in the treatment of autism

### Who can participate?

Children between the ages of 3 and 12 years with autistic disorder attending Roozbeh Hospital

### What does the study involve?

The participants will be randomly allocated into two groups. The intervention group will receive curcumin and risperidone and the control group will receive risperidone for 12 weeks.

### What are the possible benefits and risks of participating?

There is no risk in participation, but those participating in the study will benefit from the potential therapeutic effects of curcumin.

### Where is the study run from?

Roozbeh Hospital (Iran)

### When is the study starting and how long is it expected to run for?

April 2022 to May 2023

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr Mohammad Farhadi-Shahi, mohammad.farhadi.md@gmail.com

# Contact information

## Type(s)

Public, Scientific, Principal investigator

## Contact name

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# Additional identifiers

## Protocol serial number

IR.TUMS.VCR.REC.1400.4669

# Study information

## Scientific Title

Curcumin as an adjunctive treatment for irritability in children with autism spectrum disorder: a randomized, double-blind, placebo-controlled clinical trial

## Study objectives

Curcumin leads to improvement of irritability in children with autism spectrum disorder

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 01/04/2022, Institutional review board/ethics committee of Tehran University of Medical Sciences (North Kargar St, Poursina St, Tehran, 1419783151, Iran; +98 (0)2122324489; VCR@tums.ac.ir), ref: IR.TUMS.VCR.REC.1400.4669

## Study design

Randomized double-blind placebo-controlled clinical trial

## Primary study design

Interventional

## Study type(s)

Safety, Efficacy

## Health condition(s) or problem(s) studied

## Autism spectrum disorder

### Interventions

Permuted randomized blocks (blocks of four, allocation ratio 1:1) will be used by an independent party, who was not involved elsewhere in the trial, to generate the randomization codes. Allocation concealment will be achieved by sequentially numbered, sealed opaque envelopes. Patients, the physician who assessed the outcomes, and the statistician will be blinded to the treatment allocation.

Participants will be randomly allocated into two groups. The intervention group (25 people) will receive curcumin (50 to 150 micromol/day) and risperidone (1 to 3.5 mg per day) and the control group (25 people) will receive risperidone (1 to 3.5 mg per day) for 12 weeks.

Participants in both groups will receive risperidone in a similar manner. The starting daily dose of risperidone will be 0.25 mg in children weighing <20 kg and 0.5 mg in children weighing ≥20 kg.

Curcumin (ACER, Tehran, Iran) will be prescribed at 50 µmol and 100 µmol (approximately 10 mg and 20 mg) per day for patients weighing <45 kg and 45–90 kg, respectively.

### Intervention Type

Supplement

### Primary outcome(s)

Irritability is measured using the Aberrant Behavior Checklist (ABC) at baseline, week 4, week 8, and week 12

### Key secondary outcome(s)

1. Lethargy/social withdrawal is measured using the Aberrant Behavior Checklist (ABC) at baseline, week 4, week 8, and week 12
2. Stereotypic behavior is measured using the Aberrant Behavior Checklist (ABC) at baseline, week 4, week 8, and week 12
3. Inappropriate speech is measured using the Aberrant Behavior Checklist (ABC) at baseline, week 4, week 8, and week 12
4. Hyperactivity/noncompliance is measured using the Aberrant Behavior Checklist (ABC) at baseline, week 4, week 8, and week 12

### Completion date

01/05/2023

## Eligibility

### Key inclusion criteria

1. Children aged 4–12 years
2. Male or female
3. Outpatients referred to clinic with probable autistic signs and symptoms and who meet the DSM-5 criteria

### Participant type(s)

Patient

### Healthy volunteers allowed

No

**Age group**

Child

**Lower age limit**

4 years

**Upper age limit**

12 years

**Sex**

All

**Key exclusion criteria**

1. Concurrent prominent psychiatric disorder
2. Preexisting medical conditions (in particular epileptic disorders and febrile seizures)
3. Intellectual disability (IQ <70)
4. History of drug or alcohol abuse
5. History of tardive dyskinesia
6. History of taking antipsychotic medication within 6 months prior to enrollment

**Date of first enrolment**

01/01/2024

**Date of final enrolment**

01/03/2024

**Locations**

**Countries of recruitment**

Iran

**Study participating centre**

**Roozbeh Hospital**

North Kargar St, Poursina St

Tehran

Iran

1439957181

**Sponsor information**

**Organisation**

Roozbeh Hospital

ROR

<https://ror.org/019mzt973>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date