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

Submission date	Recruitment status	[X] Prospectively registered
20/11/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/11/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/11/2023	Mental and Behavioural Disorders	[ ] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

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