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 antiinflammatory 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 Prof Mohamad Farhadi-shahi

Contact details Tehran University of Medical Sciences Poursina St Tehran Iran 1419783151

+98 (0)2122324489 mohammad.farhadi.md@gmail.com

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 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

Secondary study design

Randomised controlled trial

Study setting(s) GP practice, Hospital

Study type(s) Safety, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date 01/04/2022

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

Age group Child

Lower age limit 4 Years

Upper age limit 12 Years

Sex

Both

Target number of participants 60

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

Sponsor details North Kargar St, Poursina St Tehran Iran 1439957181 +98 (0)2122324489 VCR@tums.ac.ir

Sponsor type Hospital/treatment centre

Website http://roozbehhospital.tums.ac.ir/

ROR https://ror.org/019mzt973

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The draft and data will be distributed through final report

Intention to publish date

01/04/2024

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