Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A clinical trial to compare the effects of curcumin with placebo on Attention-Deficit/Hyperactivity Disorder (ADHD) patients undergoing Ritalin treatment

Protocol summary

Summary

Objective: To compare the effects of curcumin with placebo on Attention-Deficit/Hyperactivity Disorder (ADHD) patients undergoing Ritalin treatment. Design: A double blind block randomized clinical trial. Study population: Attention-Deficit/Hyperactivity Disorder (ADHD) patients. Inclusion criteria: Aged between 7 and 15 years; diagnosis Attention-Deficit/Hyperactivity Disorder (ADHD) based on DSM-V-TR criteria; lack of mental retardation (MR), epilepsy, pervasive developmental disorder, schizophrenia, mania episode, anxiety disorders, bipolar disorder, special ability and learning disorders, and hyperactivity disorder due to organic brain syndrome (OBS) or drug reactions. Exclusion criteria: Liver and renal failure; thyroid disorder; allergy to curcumin; chronic inflammatory diseases; use of anti-inflammatory and antioxidant drugs. Sample size: 70 cases. Study intervention: The control group, children and teenagers with Attention-Deficit/Hyperactivity Disorder (ADHD) undergoing Ritalin treatment (0.1-3 mg) received 80 mg of placebo (similar components of curcumin capsules) twice a day. The intervention group, children and teenagers with Attention-Deficit/Hyperactivity Disorder (ADHD) undergoing Ritalin treatment (0.1-3 mg) received 80 mg of curcumin (Sina Drug) twice a day. Study outcome: Evaluation and comparison the effectiveness of clinical outcomes including learn, impulsivity, anxiety, hyperactivity and conduct disorder (CD) score base on questionnaire in intervention and control groups before, 4 and 8 weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050433810N1**

Registration date: **2017-05-28, 1396/03/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-28, 1396/03/07

Registrant information

Name

Marzea Rangian

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38823255

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effects of curcumin with

placebo on Attention-Deficit/Hyperactivity Disorder (ADHD) patients undergoing Ritalin treatment

Public title
The effects of curcumin on Attention-Deficit/Hyperactivity Disorder (ADHD) patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Aged between 7 and 15 years; diagnosis Attention-Deficit/Hyperactivity Disorder (ADHD) based on DSM-V-TR criteria; lack of mental retardation (MR), epilepsy, pervasive developmental disorder, schizophrenia, mania episode, anxiety disorders, bipolar disorder, special ability and learning disorders, and hyperactivity disorder due to organic brain syndrome (OBS) or drug reactions. Exclusion criteria: Liver and renal failure; thyroid disorder; allergy to curcumin; chronic inflammatory diseases; use of anti-inflammatory and antioxidant drugs.
Age
From **7 years** old to **15 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
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
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Postal code
Approval date
2015-11-18, 1394/08/27
Ethics committee reference number
IR.MUMS.fm.REC.1395.452

Health conditions studied

1

Description of health condition studied
Attention-Deficit/Hyperactivity Disorder (ADHD)
ICD-10 code
F90.0
ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
Evaluation the effectiveness of clinical outcomes including learn, impulsivity, anxiety, hyperactivity and conduct disorder (CD) score
Timepoint
before, 4 and 8 weeks after intervention
Method of measurement
Base on questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Children and teenagers with Attention-Deficit/Hyperactivity Disorder (ADHD) undergoing Ritalin treatment (0.1-3 mg) received 80 mg of placebo (similar components of curcumin capsules) twice a day.
Category
Treatment - Drugs

2

Description
Intervention group: Children and teenagers with Attention-Deficit/Hyperactivity Disorder (ADHD) undergoing Ritalin treatment (0.1-3 mg) received 80 mg of curcumin (Sina Drug) twice a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebn'e Sina Hospital
Full name of responsible person

Marzea
Street address
Ranghian
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Marzea Ranghian
Position
Psychiatrist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary

empty