Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on clinical status and metabolic profiles in children with attention deficit hyperactivity disorder undergoing Ritalin treatment

Protocol summary

Study aim

The aim of this study is to determine the effects of probiotic supplementation on clinical status and metabolic profiles in children with ADHD

Design

Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive probiotic supplements (n=20) or placebo (n=20)

Settings and conduct

Among children with ADHD referred to Kargarnejad clinic affiliated to Kashan University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in packaging. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. intervention duration: 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 8-12 years diagnosed with ADHD based on DSM-IV criteria will be included in this study. Exclusion criteria: mental disorders, bipolar disorder, pervasive developmental disorders, autism, not interested to be in research, consuming probiotic yogurt and other fermented foods, taking probiotic, antioxidant and/or anti-inflammatory supplements including vitamin E, vitamin C and omega-3 fatty acids, and taking antibiotics.

Intervention groups

Intervention group: probiotic sachet (Takgen Co., Tehran, Iran) including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Lactobacillus reuteri, 2×109 Lactobacillus fermentum, daily, for 8 weeks orally. Control group: Placebo sachet (Takgen Co., Tehran, Iran), daily, for 8 weeks orally.

Main outcome variables

ADHD rating scale (primary outcome) and inflammatory factors, biomarkers of oxidative stress, depression and anxiety (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090133941N16**
Registration date: **2017-11-01, 1396/08/10**
Registration timing: **retrospective**

Last update: **2018-04-10, 1397/01/21**
Update count: **2**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-06-05, 1396/03/15

Expected recruitment end date
2017-09-06, 1396/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of probiotic supplementation compared with the placebo on clinical status and metabolic profiles in children with attention deficit hyperactivity disorder undergoing Ritalin treatment

Public title
Effect of probiotic supplementation in treatment of children with attention deficit hyperactivity disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged between 8 and 12 years Patients diagnosed with attention deficit hyperactivity disorder based on DSM-IV criteria
Exclusion criteria:
mental disorders bipolar disorder pervasive developmental disorders autism not interested to be in research consuming probiotic yogurt, kefir and other fermented foods taking probiotic, antioxidant and/or anti-inflammatory supplements including vitamin E, vitamin C and omega-3 fatty acid taking antibiotics
Age
From **8 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Approval date
2016-09-27, 1395/07/06
Ethics committee reference number
IR.KAUMS.REC.1395.59

Health conditions studied

1

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

Primary outcomes

1

Description
ADHD rating scale
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Hs-CRP
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Elisa kit

2

Description
Nitric oxide
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Glutathione
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Total antioxidant capacity
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Hamilton Anxiety Rating scale
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Questionnaire

7

Description
depression
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: probiotic sachet (Takgen Company, Tehran, Iran) including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Lactobacillus reuteri, 2×109 Lactobacillus fermentum, daily, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo sachet (Takgen Company, Tehran, Iran), daily, for 8 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kargarnejad Clinic
Full name of responsible person
Dr. Zahra Sepehrmanesh
Street address
Ghotbe Ravandi Boulevard, Kashan
City
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Postal code
8115187159
Phone
+98 31 5546 3378
Email
Sepehrmanesh_z@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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Ghotbe Ravandi Boulevard, Kashan
City
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Hamidi_gh@kaums.ac.ir

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, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Ph.D of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

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

Data Dictionary