

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of the effectiveness of probiotic on the treatment of ADHD children

Protocol summary

Study aim

to evaluate the effect of probiotic in the treatment of ADHD children

Design

Triple blind parallel randomized controlled trial
intervention group: ADHD treatment + probiotic control
group: ADHD treatment + placebo n= 30 patients in each group

Settings and conduct

4-16 year old ADHD patients who are referred to Ibn-e-Sina psychiatric clinic enter to this study(after their parents sign the informed consent form). Patients randomly divide to 2 groups: intervention(ADHD treatment + probiotic) and control(ADHD treatment + placebo). All patients, assessors and analyzer are blind(more description about blinding is presented in the specific part for blinding)

Participants/Inclusion and exclusion criteria

4-16 year old children with ADHD, without any treatment in the last 2 months

Intervention groups

intervention group: ADHD treatment + probiotic control
group: ADHD treatment + placebo

Main outcome variables

ADHD scale using Conner's parent rating scale.
Integrated Visual and Auditory Continues Performance Test (IVA/CPT)

General information

Reason for update

As the industrial phase of the study took about two years, at the time of trial registration in IRCT, we wrote that we will use either Conner's parent rating scale or ADHD rating scale as the primary outcome in clinical phase. After completing the industrial phase, it was decided to use the Conner's parent rating scale (CPRS). So, we updated this part

Acronym

IRCT registration information

IRCT registration number: **IRCT20181022041407N1**

Registration date: **2018-11-02, 1397/08/11**

Registration timing: **prospective**

Last update: **2023-05-20, 1402/02/30**

Update count: **1**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

Maryam Emadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3882 9262

Email address

emadzadehm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of probiotic on the treatment of ADHD children

Public title

evaluation the effect of probiotic on treatment of ADHD children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

4-16 year old children New case of ADHD diagnosed by psychiatrist

Exclusion criteria:

History of treatment because of ADHD in the last 2 months Other psychological problems Mental Retardation

Age

From **4 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization Randomization Method: excel software or other randomization websites Allocation Concealment: opaque envelope

Blinding (investigator's opinion)

Triple blinded

Blinding description

After the description about the method and aim of the study and informed consents of parents, randomization will be done. The type of treatment is written with odds and even number in separate papers and placed in an opaque envelope. After the psychiatrist visits the patients, if the patients have the inclusion criteria, the method of the study will describe to the parents. If they agree to participate in this study, the informed consent form must be completed. Then the psychiatrist will take an envelope and write the patients characteristic with the special number(odds or even) in the list. So, patients and psychiatrist only know the number (not the intervention or control group). After the special time, the assessor evaluates the children with the specific questionnaire. He does not know which group the patient is (blind). Then the complete data will b presented to the analyzer for data analysis. In the datasheet the group will type as odd/even numbers(not the group names), so the analyzer is blind too.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Research Ethics Committee, School of Medicine- Mashhad University of Medical Sciences

Street address

Azadi Square, University Campus, Faculty of Medicine

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2018-09-05, 1397/06/14

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.030

Health conditions studied

1

Description of health condition studied

ADHD

ICD-10 code

F90.9

ICD-10 code description

Attention-deficit hyperactivity disorder, unspecified type

Primary outcomes

1

Description

evaluation of ADHD scale with Conner's parent rating scale

Timepoint

Baseline, 4 and 8 weeks after the first visit

Method of measurement

Conner's parent rating scale

Secondary outcomes

1

Description

Integrated Visual and Auditory Continues Performance Test (IVA/CPT)

Timepoint

Baseline and after 8 weeks

Method of measurement

A computerized standardized test consists of both auditory and visual parts

Intervention groups

1

Description

Intervention group: ADHD treatment + probiotic

Category

Treatment - Drugs

2

Description

Control group: ADHD treatment + placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn-e-Sina Hospital, Psychiatric Clinic

Full name of responsible person

Maryam Emadzadeh

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Ibn-e-Sina Hospital, Hor-e-Ameli Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Grant name

Mashhad University of Medical Sciences

Grant code / Reference number

961476

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

80

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

2

Sponsor

Name of organization / entity

Research Institute of Food Science and Technology

Full name of responsible person

Mahdi Ziaratnia

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km. 12- Mashhad/ Quchan Highway

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Email

info@rifst.ac.ir

Web page address

<https://www.rifst.ac.ir/>

Grant name

Research grant of Research Institute of Food Science and Technology

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Institute of Food Science and Technology

Proportion provided by this source

20

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

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Emadzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Data Dictionary

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