Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
Phone
+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
Street address
Ibn-e-Sina Hospital, Hor-e-Ameli Street
City
Mashhad
Province
Razavi Khorasan
Postal code
919583134
Phone
+98 51 3711 2701
Email
maryamemadzadeh@yahoo.com
Web page address
http://sina.mums.ac.ir/index.php

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Ghoreyshi Building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
13944-91388
Phone
+98 51 3841 2081
Fax
+98 51 3841 3006
Email
presidentoffice@mums.ac.ir
Web page address
http://www.mums.ac.ir/
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
Street address
km. 12- Mashhad/ Quchan Highway
City
Mashhad
Province
Razavi Khorasan
Postal code
9185176933
Phone
+98 51 3542 5421
Fax
+98 51 3542 5406
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

Street address

Department of Community Medicine, Faculty of Medicine, University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3882 9262

Email

maryamemadzadeh@yahoo.com

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

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Assistant Professor

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Email

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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