Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation The effect of Probiotics in Reducing Behavioral Symptoms and Severity of Autism in Children and Adolescents with Autism Spectrum Disorder

Protocol summary

Study aim

The effect of probiotics on the symptoms and severity of autism disorder will be evaluated.

Design

A one-way clinical trial of 70 autistic children 3 to 18 years of age who are conveniently available to participate in the study.

Settings and conduct

70 children with autism spectrum disorder between the ages of three to 18 years old who is referred to the children and adolescent psychiatric clinic of Imam Hossein Hospital in Tehran or Iran's Autism Association will be selected. This sample will first be evaluated using two CARS and ATEC questionnaires to examine the symptoms and determine the severity of the disorder. Then all participants will be treated once a day for four weeks with Kidilact probiotics. At the end of the month, children will be evaluated again by the CARS and ATEC questionnaires, and the symptoms and response rates will be reviewed. The results will be analyzed statistically and will be compared with the beginning of the study.

Participants/Inclusion and exclusion criteria

Children from 3 to 18 year old with Autism Spectrum Disorder who do not have chronic infectious disease and AIDS without taking antifungal medication, antibiotic, anti-inflammatory drugs, corticosteroids and anti-diarrheal drugs, enrolled in the study after receiving consent from their parent or caretaker.

Intervention groups

After four weeks, the effect of Kid Lakt on the symptoms and severity of autism in children is evaluated.

Main outcome variables

Changes in the number of symptoms of autism in response to probiotics; changes in the severity of autism in response to probiotics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130504013215N2**
Registration date: **2018-05-14, 1397/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-14, 1397/02/24**
Update count: **0**

Registration date

2018-05-14, 1397/02/24

Registrant information

Name
Katayoon Razjouyan
Name of organization / entity
Behavioral Sciences Research Center, Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 7755 1023
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k_razjouyan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation The effect of Probiotics in Reducing Behavioral Symptoms and Severity of Autism in Children and Adolescents with Autism Spectrum Disorder

Public title
Probiotics Effect in Reducing Behavioral Symptoms and Severity of Autism

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with autism between 3 and 18 years of age
Exclusion criteria:
Suffering from chronic infectious diseases Congenital metabolic disorders HIV and Congenital Immunodeficiency Disorder Under treatment with anti-fungal drugs, antibiotics, anti-inflammatory drugs, corticosteroids, anti-diarrheal compounds, chemotherapy

Age
From **3 years** old to **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshty University of Medical Sciences
Street address
Imam Hossein Hospital, Madani st.
City
Tehran
Province
Tehran
Postal code
16117763141
Approval date
2016-11-13, 1395/08/23
Ethics committee reference number
IR.SBMU.RETECH.REC.1395.548

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorder
ICD-10 code
F84.0
ICD-10 code description
Childhood autism

Primary outcomes

1

Description
Change in symptoms of autism disorder in the CARS questionnaire
Timepoint
When entering the study and 8 weeks after starting treatment
Method of measurement
CARS questionnaire at the beginning and the end of the study

2

Description
Change in severity of autism disorder in the ATEC questionnaire
Timepoint
When entering the study and 8 weeks after starting treatment
Method of measurement
ATEC questionnaire at the beginning and the end of the study

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Children with autism disorder are treated with Kidilact probiotics Sache for four weeks. Before entering the study, they filled out the CARS and ATEC questionnaires to measure the symptoms and severity of the disorder. Kidilact Sache is specific for children over 2 years of age that contains high levels of seven beneficial bacterial strains, including the specific strain of children "Bifidobacterium infantis" along with probiotic fructooligosaccharide (contributing to the

growth and activity of probiotics). Its formula is specially designed for children to eat it easily. It is consumed by a sachet a day. After 4 weeks, the effect of the drug on the reduction of symptoms and severity of autism disorder is measured by the CARS and ATEC questionnaires.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital- Autism Society of Iran

Full name of responsible person

Katayoon Razjouyan

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Shahid Madani Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

30

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Katayoon Razjouyan

Position

Assistant Professor of Child and Adolescent Psychiatry

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Position

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Latest degree

Subspecialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Demographic information such as gender and age, without mentioning the name is shared.

When the data will become available and for how long
The access period starts from 2019.

To whom data/document is available
Researchers on Autism Spectrum Disorders

Under which criteria data/document could be used
For use in similar studies on children with developmental disorders

From where data/document is obtainable
Use the responsible person's email

What processes are involved for a request to access data/document
After the presentation of evidence from well-known research centers to conduct a similar study, files will be available up to one month.

Comments