Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Synbiotic on reducing insulin resistance in overweight or obese children

Protocol summary

Study aim
Determining the effect of synbiotics on reducing insulin resistance in overweight or obese children

Design
A clinical trial with parallel groups, double-blinded, randomized (permuted block randomization), phase 3 on 40 children with obesity/overweight, using www.sealedenvelope.com for randomization.

Settings and conduct
This study is performed in Ali Asghar Children's Hospital. Obese or overweight children are randomly assigned into two groups. In the first group, children receive Synbiotic. In the second group, children receive placebo. In this study, children and physicians did not know the type of medication they received.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range between 4 -18 years, Obese or overweight children: Obese children, children with a BMI of more than 95% and overweight children, children with a BMI between 85-95%, Children with insulin resistance (HOMA-IR : > 2.5 = Positive for IR) Exclusion criteria: Children who developed obesity following syndromic disorder or endocrine disorders, Physical disability, Taking corticosteroids, Treated with metformin, Under special treatment or diet, Acute pancreatitis, History of allergies.

Intervention groups
In the intervention group, Children receive 1 sachet of probiotic daily (Kidi Lact, manufactured by Zist Takhmir Company, Iran) for 8 weeks. in the Control group: Children received one placebo sachet (manufactured by Zist Takhmir Company, Iran) daily for 8 weeks.

Main outcome variables
Insulin Resistance level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211226053529N1**
Registration date: **2021-12-31, 1400/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-31, 1400/10/10**
Update count: **0**

Registration date
2021-12-31, 1400/10/10

Registrant information

Name
Farzaneh Rohani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2304 6253

Email address
rohani.f@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-04-19, 1401/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Synbiotic on reducing insulin resistance in overweight or obese children

Public title

Effect of Synbiotic on reducing insulin resistance in overweight or obese children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range between 4 -18 years Obese or overweight children: Obese children, children with a BMI of more than 95% and overweight children, children with a BMI between 85-95% Children with insulin resistance (HOMA-IR : > 2.5 = Positive for IR)

Exclusion criteria:

Children who developed obesity following synromic disorder or endocrine disorders Physical disability Taking corticosteroids Treated with metformin Under special treatment or diet Acute pancreatitis History of allergies

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method is used with blocks of sizes six and four. The website https://www.sealedenvelope.com is used to create a randomization sequence. Each random sequence generated contains a unique code for concealment. The drug regimen is placed in envelopes according to random sequence, and after sealing it on the envelopes, the specific number created by the site is written and the envelopes are randomly placed in a box.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blinded: both the patient and the doctor are unaware of the type of medication. Method of blinding patients: Synbiotic supplement is in the form of sachets, placebo sachets are exactly similar to the appearance, taste and smell of Kidi Lact and (produced by Zist Takhmir Company). Physician blinding method: sealed envelopes created by the Company are provided to a researcher who does not interfere in choosing the type of drug. After entering the study and collecting their baseline information from the physician, the individuals send them to the researcher to get the medicine, and the researcher will give one of the envelopes to the patients, and then in the sheet that is kept with the researcher, it is specified that What medicine has each patient taken.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Next to the Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-11-21, 1400/08/30

Ethics committee reference number

IR.IUMS.FMD.REC.1400.489

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Insulin Resistance level

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

HOMA-IR.Index (µU/ml)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children receive 1 sachet of probiotic daily (Kidi Lact, manufactured by Zist Takhmir Company, Iran) for 8 weeks.

Category
Treatment - Drugs

2

Description
Control group: Children received one placebo sachet (manufactured by Zist Takhmir Company, Iran) daily for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Aliasghar Children's Hospital
Full name of responsible person
Rana Droudian
Street address
No.193, Zafar St, Modares Highway,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Rana Drodian
Position
Fellow
Latest degree
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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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