# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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

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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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**Province**
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**Postal code**
1919816766
**Phone**
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dr.r.doroudian@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Hosein Keivani
**Street address**
Shahid Hemmat Highway next to the Milad tower
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**Phone**
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keivani.h@iums.ac.ir
**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**
Specialist
**Other areas of specialty/work**
Pediatrics
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## Person responsible for scientific inquiries

**Contact**
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**Position**
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**Latest degree**
Specialist
**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Rana Drodian

**Position**

Fellow

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email**

dr.r.doroudian@gmail.com

## 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