Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effects of probiotic on clinical indexes of obesity in obese children

Protocol summary

Summary
In this study we aim to evaluate the effects of Probiotic on obesity in children. The subjects are included 46 overweight and obese children aged between 6-15 years. Subjects will be selected from referral cases of digestive and endocrine pediatric clinic and were randomly allocated in two groups, treatment and placebo. Inclusion criteria: overweight or obese children aged 6-15 years referring to Pediatric gastrointestinal or endocrine clinics. Exclusion criteria: Having any chronic disease such as diabetes, thyroid disorders, cardiovascular or digestive disorders Intervention group followed a regime including a weight loss diet, exercise program and synbiotic capsules while placebo group had the same diet, activity schedule and received placebo capsules instead of synbiotic. The main outcomes are growth indices.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201509244976N4**
Registration date: **2015-10-12, 1394/07/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2015-10-12, 1394/07/20

Registrant information
Name
Hamid Ahanchian
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 3801 2469
Email address
ahanchianh@mums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date
2012-04-03, 1391/01/15

Expected recruitment end date
2016-01-05, 1394/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of probiotic on clinical indexes of obesity in obese children

Public title
Effects of probiotics on obesity in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: overweight or obese children aged 6-15 years refering to Pediatric Gastrointestinal or Endocrine clinics Exclusion criteria: Having any chronic disease such as diabetes; thyroid disorders; cardiovascular or digestive disorders; did not follow the intervention program regularly.

Age
From **6 years** old to **15 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomized by Table of randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committe of Mashhad university of Medical Sciences
Street address
Ghoreyshi Building, Daneshgah streeet, Mashhad Iran
City
Mashhad
Postal code
Approval date
2011-09-28, 1390/07/06
Ethics committee reference number
891011

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66
ICD-10 code description
Obesity

Primary outcomes

1

Description
Height, weight and waist circumference.
Timepoint
Monthly for 3 months
Method of measurement
Height and weight were measured with a portable stadiometer and portable digital weight

Secondary outcomes

1

Description
BMI
Timepoint
Monthly for 3 months
Method of measurement
BMI formulla

Intervention groups

1

Description
Intervention group : Diet plus exercise program plus Synbiotic capsules (Protexin company, London, England) were composed of prebiotic (Fructooligosaccharides), and 100 million CFU combination of Lactobacillus casei, Lactobacillus rhamnosus, Streptococcus thermophilus, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium infantis (child specific) and Lactobacillus bulgaricus daily for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Diet plus exercise program plus Placebo for 12 weeks in control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem educational hospital
Full name of responsible person
Dr Hamid Ahanchian
Street address
Ghaem Hospital, Ahmad abad Ave. , Taghabad sq. , Mashhad, Iran
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for research, Mashhad University of medical sciences.
Full name of responsible person
Dr Ramezani
Street address

Ghoreishi bulduing, Daneshgah Street, Mashhad, Iran Mashhad Khorasan Iran, Islamic Republic Of

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice chancellor for research, Mashhad University of medical sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Ahanchian

Position

Associate professor

Other areas of specialty/work

Street address

Ghaem hospital, Ahmad Abad blvd, Taghiabad sq. , Mashhad iran mashhad Khorasan Iran, Islamic Republic Of

City

Mashhad

Postal code

Phone

+98 51 1801 2469

Fax

Email

ahanchianh@mums.ac.ir; hamidahanchian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University odf Medical Sciences

Full name of responsible person

Hamid Ahanchian

Position

Associate professor

Other areas of specialty/work

Street address

Ghaem hospital, Ahmad Abad blvd, Taghiabad sq. , Mashhad iran mashhad Khorasan Iran, Islamic Republic Of

City

Mashhad

Postal code

Phone

+98 915 311 2207

Fax

Email

Ahanchianh@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty