

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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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.

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

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

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 referring 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

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Person responsible for updating data

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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