

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of synbiotic supplement on obesity, cardiovascular disease risk factors and inflammatory factors in 6-18 years old overweight and obese children.

Protocol summary

Summary

The objective of this randomized double-blind placebo controlled trial is to investigate the effect of symbiotic supplementation on the metabolic outcomes of obesity in obese and overweight children. Subjects with obesity and overweight will be recruited from medical clinics of obesity including 70 individuals. Subjects will be randomly assigned to receive either synbiotics capsule or corn starch placebo capsules for 8 weeks.

Anthropometric measurements (weight, height, waist and hip and neck circumference, waist to hip ratio), biochemical parameters (lipid profile including total cholesterol, LDL and HDL cholesterol and triglyceride concentrations, fasting glucose , IL-6 ,TNF- α ,hs-CRP,adiponectin)and blood pressure, dietary data obtained from twice 3-day food records and physical activity data obtained from physical questionnaire will be measured before and after treatment and compared between groups. Also to follow up the bacterial colonization in cases gut, Stool samples were collected and analysis from both case and control groups on the first, 15th ,and 60th days of study.

General information

Acronym

Synbiotics and obesity in children

IRCT registration information

IRCT registration number: **IRCT201103081434N4**

Registration date: **2012-07-05, 1391/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-05, 1391/04/15

Registrant information

Name

Roya Kelishadi

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic supplement on obesity, cardiovascular disease risk factors and inflammatory factors in 6-18 years old overweight and obese children.

Public title

Synbiotics on obesity and overweight in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children with BMI \geq 85 centiles and age

between 6-18 years old. Exclusion criteria: any disease that influence metabolic parameters in this trial (liver, cardiovascular, kidney or gastrointestinal diseases,pulmonary and diabetes); any special diet and drug; any side effects from supplement like allergy; Diarrhea; severe vomiting,Malabsorption syndrome and chronic GI disease; infection and high dose antibiotics.

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor for Research, Isfahan University Of Medical Sciences

Street address

Isfahan-hezar jarib st.-Isfahan University Of Medical Sciences

City

Isfahan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

189139

Health conditions studied

1

Description of health condition studied

obesity and overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

bacterial count in stool

Timepoint

begining of study, 2 weeks after begining, at the end of the study

Method of measurement

bacterial count in MRS media

Secondary outcomes

1

Description

Antropometric indicators (Weight, Height, BMI, Waist circumference, Hip circumference,Neck circumference,Wrist circumference, Waist to Hip Ratio)

Timepoint

Baseline and at the end of intervention

Method of measurement

Physical exam

2

Description

Serum inflammatory values (IL-6 ,TNF- α ,Adiponectin, hs-CRP)

Timepoint

Baseline and at the end of intervention

Method of measurement

hs-CRP assess with Immunoturbidometric method and IL-6 & TNF- α ,Adiponectin with Eliza method

3

Description

Fasting serum glucose values

Timepoint

Baseline and at the end of intervention

Method of measurement

Enzymatic method, Automatic analyzer

4

Description

Fasting srum lipid profile (LDL,HDL,total cholesterol,TG)

Timepoint

Baseline and at the end of intervention

Method of measurement

Enzymatic method, with special kits for assessing TG, HDL, Total cholestrol and Friedewald equation for assessing LDL cholestrol

5

Description

Blood pressure

Timepoint

Baseline and at the end of intervention

Method of measurement

Manometer

Intervention groups**1****Description**

Intervention group :consume Synbiotic, 1 capsule daily for 8 weeks (each contains 108 cfu/100gr bacteria)

Category

Treatment - Drugs

2**Description**

control group :consume 1 capsule each day for 8 weeks and each capsule involved maltodextrin

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children Clinics belongs to Isfahan University of Medical Science

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Peiman Adibi

Street address

Isfahan University of Medical Sciences

City

Isfahan

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, Isfahan 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****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

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Master degree student

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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