Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 questionary 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

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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 ≥ 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 Immunotorbidometric 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
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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