

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of chitosan supplementation on some appetite regulating hormones, intestinal microbiota, anthropometric indices and blood sugar and lipid control indices in overweight and obese adolescents

Protocol summary

Study aim

Determine the effect of Chitosan supplementation on some appetite regulating hormones, intestinal microbiota, anthropometric indices and blood sugar and lipid control indices in overweight and obese adolescents

Design

-A 12-week double-blind, randomized parallel clinical trial on 60 overweight and obese adolescents

Settings and conduct

This study is a double-blind clinical trial that will be performed to determine the effect of Chitosan supplementation on intestinal microbiome, appetite regulating hormones, anthropometric factors, lipid profile and carbohydrate metabolism in overweight and obese adolescents. After the approval of the proposal in the ethics committee of IUMS, adolescents who refer to the Obesity Clinic of Mofid Hospital will be invited to participate in the study. Eligible individuals will be interviewed in person and the goals, methods and importance of conducting the study will be explained in detail to each of them and their parents. They will be divided into 2 groups (placebo group, Chitosan group) and they are asked to take 3 grams of supplement or placebo daily, half an hour before lunch with 1 glass of water.

Participants/Inclusion and exclusion criteria

Girls and boys 10 to 18 years old with a Z score of body mass index higher than 1 and less than 3 for age and sex who do not have cardiovascular disease, type 1 or 2 diabetes, liver disease, gastrointestinal (celiac, IBD or IBS) or Kidney with all metabolic disorders including PKU, MSUD, urea cycle disorders). They also do not have a history of gastrointestinal surgery, taking medications or supplements that affect appetite, weight or metabolism, and have not followed any weight loss diet or heavy exercise program in the past 6 months.

Intervention groups

-3 grams of Chitosan powder daily for 30 minutes to 1 hour before lunch for 12 weeks

Main outcome variables

Weight, BMI z score, waist circumference and NPY level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N57**

Registration date: **2021-06-20, 1400/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-20, 1400/03/30**

Update count: **0**

Registration date

2021-06-20, 1400/03/30

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8862 2755

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-21, 1400/02/31

Expected recruitment end date

2021-10-21, 1400/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chitosan supplementation on some appetite regulating hormones, intestinal microbiota, anthropometric indices and blood sugar and lipid control indices in overweight and obese adolescents

Public title

The effect of chitosan supplementation on some appetite regulating hormones, intestinal microbiota, anthropometric indices and blood sugar and lipid control indices in overweight and obese adolescents

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to cooperate Overweight and obese girls and boys 10 to 18 years old with Z score body mass index higher than 1 and less than 3 for age and sex

Exclusion criteria:

Use of probiotic or prebiotic or synbiotic supplements for the past three months or any foods fortified with these supplements • Take any antibiotics 3 months before the study • Have type 1 or 2 diabetes, cardiovascular disease or hepatic, gastrointestinal (Celiac, IBD or IBS) or renal disorders or all metabolic disorders including PKU, MSUD, urea cycle disorders or .. • History of gastrointestinal surgery • Taking drugs or supplements that affect appetite, weight or metabolism at least three months before the study (such as medications that affect carbohydrate, protein or fat metabolism, and medications that reduce or increase appetite or food intake, including herbal supplements) • Have any weight loss diet or any program heavy exercise in the last 6 months • Pregnancy and lactation • Smoking (more than one cigarette per week or more than 200 cigarettes in a lifetime) • Having any allergies to chitosan or shrimp • Exclusion criteria: • 1- Having any acute illness • 2- Occurrence of any accident that affects a person's health • 3- Taking antibiotics while studying • 4- Low acceptance rate more than 80% • 5- Not following the intervention • 6- Immigration • 7- Leaving the study based on the personal desire of the participants or their parents

Age

From **10 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by the restricted randomization method: first people in terms of age and sex in quadratic blocks (A, B, C and D) will be placed. Then, random allocation of people in each block to intervention and control groups will be done. random allocation of individuals to intervention and control groups, will be performed by means of software.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double-blindness, so that researchers and all participants are unaware of intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

In order to apply concealment in the randomization process, individual codes will be used on the medicine boxes and the desired code will also be produced by the software.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.IUMS.REC.1400.104

Health conditions studied**1****Description of health condition studied**

Obese or overweight adolescents

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Weight

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Seca scale

2

Description

Body mass index(BMI)

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Weight (kg) divided by height squared (square meters)

3

Description

Waist circumference

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Measuring tape

4

Description

Serum of Neuropeptide Y (NPY)

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Blood sampling and measurement by ELISA method

Secondary outcomes

1

Description

Stool microbiome

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

DNA extraction kit

2

Description

BMI z score

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Calculation

3

Description

Serum leptin

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Blood sampling and measurement by ELISA method

4

Description

Serum adiponectin

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Blood sampling and measurement by ELISA method

5

Description

Serum cholesterol, triglyceride, LDL and HDL levels

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Blood sampling and measurement by ELISA method

6

Description

Serum glucose levels

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Blood sampling and measurement by ELISA method

7

Description

Serum insulin levels

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Blood sampling and measurement by ELISA method

8

Description

Serum HOMA-IR

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

Blood sampling and measurement by ELISA method

Intervention groups

1

Description

Intervention group: 3 grams of chitosan powder daily for 30 minutes to 1 hour before lunch for 12 weeks

Category

Treatment - Other

2

Description

Control group: 3 g of maltodextrin daily 30 minutes to 1

hour before lunch for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Hospital

Full name of responsible person

Aliakbar Sayyari

Street address

No. 1057, Mofid Children's Hospital, above Hosseinieh Ershad, Shariati St., Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Sayyed Abbas Motevallian, deputy head of Research and technology, Iran university of medical sci

Street address

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research-m@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

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

Dr.Farzad Shidfar

Position

Full Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main implications can be shared at the end of the study.

When the data will become available and for how long

The access period will be 6 months after the results are published.

To whom data/document is available

The data from this study will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

6 months after the publication of the articles obtained from the data of this project, at the request of the person in charge of the project and his consent, the study data can be made available to researchers.

From where data/document is obtainable

Applicants can contact the responsible author via email or the following mailing address to obtain the required data. Postal address: Tehran-Hemmat Highway-Iran University of Medical Sciences-Faculty of Health-Department of Nutrition. Contact number: 00982188622755. Email: shidfar.f@iums.ac.ir

What processes are involved for a request to access data/document

Applicants will be able to access the study data by sending an email to the responsible author within a maximum of one week.

Comments