Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

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 adibonectin
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.

City

Tehran

Province

Tehran

Postal code

1546815514

Phone

+98 21 2222 7021

Email

info-mch@sbmu.ac.ir

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

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Email

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

Street address

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

14496145535

Phone

+98 21 8860 7945

Email

shidfar.f@iums.ac.ir

Person responsible for scientific 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

Street address

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8860 7945

Email

shidfar.f@iums.ac.ir

Person responsible for updating data

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
Street address
Hemmat Highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8860 7945
Email
shidfar.f@iums.ac.ir

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