Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effectiveness assessment of a probiotic supplement on weight control in obese adults: a double blind clinical trial

Protocol summary

Study aim
The aim of this study is to prepare and produce effective probiotic formulations in obese adults and to evaluate their effectiveness on anthropometric indices, lipid profile, glycemic control, liver enzymes, inflammatory factors and GLP1 hormone.

Design
Double-blind Randomized clinical trial (both patients and researchers) with a parallel group design.

Settings and conduct
From outpatients with obesity referred to the nutrition clinic of Shariati Hospital affiliated to Tehran University of Medical Sciences, 60 patients will be selected based on inclusion and exclusion criteria. Participants and researchers are unaware of the allocation of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken from patients at the beginning of the study and 12 weeks after the intervention.

Participants/Inclusion and exclusion criteria
This randomized clinical trial will be performed on 60 eligible obese adults. Subjects are randomly divided into one of two groups: supplements and placebo. The duration of the intervention is 3 months, and people take supplements or placebos in addition to a low-calorie weight loss diet. At the beginning and end of the study, people have blood and stool tests and are examined for anthropometric indicators and food intake (24-hour recall questionnaire).

Intervention groups
Intervention group: Probiotic supplement capsule made by Tak Gene Pharmaceutical Company, twice a day with low calorie diet (500 kcal less than the person energy need), for three months Control group: Placebo, twice daily with low calorie diet (500 kcal less than the person energy need), for three months

Main outcome variables
Weight Body Mass Index Waist circumference and hip circumference Intestinal microbiota

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090420001825N3**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **prospective**

Last update: **2021-04-08, 1400/01/19**
Update count: **1**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Shirin Hasani-Ranjbar

Name of organization / entity

Country
Iran (Islamic Republic of)

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sh_hasani@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-06, 1399/07/15

Expected recruitment end date
2021-03-21, 1400/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effectiveness assessment of a probiotic supplement on weight control in obese adults: a double blind clinical trial

Public title
The effect of probiotic supplement on weight in obese people
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range: 20 to 55 years Body mass index: 30 to 40 kg/m2 Interest in participating in the project
Exclusion criteria:
unwillingness to cooperate pregnancy and lactation smoking cardiovascular disease (history of myocardial infarction and use of digoxin and warfarin) renal disease (creatinine above 2 mg/dL and GFR less than 30) Liver disease (liver enzyme levels two and a half times normal) inflammatory bowel disease such as colitis diabetes cancer history of gastrointestinal surgery use of antibiotics during the two months before the start of the study and during the study taking multivitamin supplements during the study common use of probiotics and prebiotics during the month before the start of the study common use Anti-inflammatory drugs during the month before the start of the study use of weight loss drugs in the last 3 months history of special diet for weight loss in the last 3 months history of mental illness
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization is performed in order to balance the number of samples assigned to each of the study groups. Web randomization (https://www.sealedenvelope.com) is used for this purpose. The number and characteristics of the participants are entered in the desired position and the individuals are randomly assigned to one of the two intervention and placebo groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants, researchers, and clinical caregivers were unaware that each participant in the study was in the main intervention group (receiving a probiotic supplement) or a placebo (without a probiotic). Supplements and placebos are packaged exactly the same and separated by code. Therefore, people cannot identify which group they belong to.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Endocrinology and Metabolism Research Institute afilliated to Tehran University
Street address
Chamran Highway, Jalal Al-Ahmad Highway, Shariati Hospital, Fifth Floor, Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences, Obesity and Eating Habits Research Center
City
Tehran
Province
Tehran
Postal code
1411713137
Approval date
2019-03-07, 1397/12/16
Ethics committee reference number
IR.TUMS.EMRI.REC.1398.001

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
weight
Timepoint
Beginning and end of the intervention
Method of measurement
Digital scale

2

Description
Body mass index
Timepoint
Beginning and end of the intervention
Method of measurement

Formula

3

Description
Waist circumference and hip circumference
Timepoint
Beginning and end of the intervention
Method of measurement
Tape meter

Secondary outcomes

1

Description
Waist to hip ratio
Timepoint
Beginning and end of the intervention
Method of measurement
Formula

2

Description
fasting glucose blood
Timepoint
Beginning and end of the intervention
Method of measurement
Autoanalyzer

3

Description
insulin
Timepoint
Beginning and end of the intervention
Method of measurement
Eliza

4

Description
Total cholesterol
Timepoint
Beginning and end of the intervention
Method of measurement
Spectrophotometry

5

Description
HDL
Timepoint
Beginning and end of the intervention
Method of measurement
Spectrophotometry

6

Description
LDL
Timepoint
Beginning and end of the intervention
Method of measurement
Spectrophotometry

7

Description
TG
Timepoint
Beginning and end of the intervention
Method of measurement
Spectrophotometry

8

Description
Liver enzymes (ALT and AST)
Timepoint
Beginning and end of the intervention
Method of measurement
Colorimetric test

9

Description
hsCRP
Timepoint
Beginning and end of the intervention
Method of measurement
Eliza

10

Description
GLP1
Timepoint
Beginning and end of the intervention
Method of measurement
Eliza

11

Description
Intestinal microbiota
Timepoint
Beginning and end of the intervention
Method of measurement
Real-time polymerase chain reaction

Intervention groups

1

Description
Intervention group: Receive a weight loss diet and probiotic supplement for 12 weeks, A weight loss diet (500 kcal less than the daily requirement and the composition of the prescribed diet was 55% carbohydrate, 30% fat and 15%protein) is prescribed for the patient and a probiotic supplement manufactured by the TAKGENE pharmaceutical company (Contains Lactobacillus plantarum, Lactobacillus rhamnosus, Lactobacillus casei, Bifidobacterium langum, 10 to 8 or 9

cfu per capsule) twice per day is prescribed for 12 weeks.

Category

Treatment - Other

2

Description

Control group: Receive weight loss diet and placebo for 12 weeks, The usual weight loss diet (500 kcal less than the daily requirement and the composition of the prescribed diet was 55% carbohydrate, 30% fat and 15%protein) is prescribed for the patient and the placebo (containing maltodextrine and magnesium stearate) is prescribed in the same size and shape as supplements made by TAKGENE Pharmaceutical Company, twice per day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Obesity Clinic of Shariati hospital

Full name of responsible person

Shirin Hasani-Ranjbar

Street address

Chamran Highway, Jalal Al-Ahmad Highway, Shariati Hospital, Fifth Floor, Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences, Obesity and Eating Habits Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences

Full name of responsible person

Neda Mehrdad

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Chamran Highway, Jalal Al-Ahmad Highway, near Shariati Hospital, Endocrinology and Metabolism Research Institute

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology and Metabolism Research Institute, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hanieh-Sadat Ejtahed

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable