

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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)

Phone

+98 21 8822 0076

Email address

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 affiliated 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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8822 0038

Email

sh_hasani@sina.tums.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411713137

Phone

+98 21 8863 1298

Email

emri-research@tums.ac.ir

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

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

Phone

+98 21 8822 0038

Fax**Email**

haniejtahed@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact**

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shirin Hasani-Ranjbar

Position

Professor of Endocrinology & Metabolism

Latest degree

Ph.D.

Other areas of specialty/work

Endocrine

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

Phone

+98 21 8822 0038

Email

sh_hasani@sina.tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hanieh Malmir

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Nutrition

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

Phone

+98 21 8822 0076

Email

hanieh.malmir@gmail.com

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