

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Study of the effect of metformin and prebiotic on weight and gut microbiota composition in obese women

Protocol summary

Study aim

The objective of this randomized controlled clinical trial is to investigate the effect of prebiotic and metformin on the gut microbiota in obese women.

Design

This randomized trial is conducted with parallel group design.

Settings and conduct

Samples of this study will be recruited from obesity clinic in Shariati Hospital in Tehran and participants will be assigned in three groups randomly. In this double-blind trial, participants and investigators are blinded and the packages of drugs are identical.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 20 to 45 years; BMI in the range of 30-40 kg/m²; Exclusion criteria: Pregnancy and lactation; Smoking; Chronic cardiovascular disease, Kidney disorders, liver disorders, inflammatory bowel diseases, diabetes, cancer and history of digestive tract surgery; The incidence of acute gastrointestinal disorder.

Intervention groups

Patients will be randomly assigned to receive metformin or prebiotic or placebo twice per day along with the hypo-caloric diet for two months.

Main outcome variables

Anthropometric measurements, gut microbiome analysis and measurement of faecal short-chain fatty acid concentrations and serum biochemical variables will be done before and after treatment and will be compared among three groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090420001825N2**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **prospective**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

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

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of metformin and prebiotic on weight and gut microbiota composition in obese women

Public title

The effect of metformin and prebiotic on gut microbiota composition in obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 20 to 45 years; BMI in the range of 30-40 kg/m²; Interest in participating in the study

Exclusion criteria:

Pregnancy and lactation; Smoking; Chronic cardiovascular disease (history of CHF and using digoxin and warfarin drugs), kidney disorders, liver disorders, inflammatory bowel disease, diabetes, cancer and history of digestive tract surgery; A history of acute and chronic diarrhea over a month before the start of the study; The incidence of acute gastrointestinal disorder; Antibiotic therapy within the two months prior to or during the study; Multivitamin supplementation during the study; Routine use of probiotics and prebiotics products over a month before the start of the study; Routine use of anti-inflammatory drugs within a month prior to the start of the study; Taking weight loss drugs over the past 3 months; History of specific weight loss diet over the past 3 months; History of mental illness

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: Block randomization Unit of randomization: individual The random sequence was built by computer software and allocation concealment was carried out using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, investigators and healthcare providers are blinded in this study. Supplements and placebo are packaged identically and they are separated by code.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical science

Street address

Jalale Ale Ahmad Ave.

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.TUMS.EMRI.REC.1395.0090

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

Gut microbiota

Timepoint

baseline, endpoint

Method of measurement

Real time PCR, 16S rRNA sequencing

2

Description

weight

Timepoint

baseline, endpoint

Method of measurement

Digital scale

3

Description

Body mass index

Timepoint

baseline, endpoint

Method of measurement

Formula

4

Description

waist and hip circumferences

Timepoint

baseline, endpoint

Method of measurement

Tape

5**Description**

Fecal short-chain fatty acids concentrations

Timepoint

baseline, endpoint

Method of measurement

gas chromatography

Secondary outcomes**1****Description**

Glucose

Timepoint

baseline, endpoint

Method of measurement

autoanalyzer

2**Description**

Insulin

Timepoint

baseline, endpoint

Method of measurement

ELISA

3**Description**

Total cholesterol

Timepoint

baseline, endpoint

Method of measurement

spectrophotometric method

4**Description**

triglycerides

Timepoint

baseline, endpoint

Method of measurement

spectrophotometric method

5**Description**

LDL cholesterol

Timepoint

baseline, endpoint

Method of measurement

spectrophotometric method

6**Description**

HDL cholesterol

Timepoint

baseline, endpoint

Method of measurement

spectrophotometric method

7**Description**

Liver enzymes

Timepoint

baseline, endpoint

Method of measurement

colorimetric tests

8**Description**

hsCRP

Timepoint

baseline, endpoint

Method of measurement

ELISA

9**Description**

lipoprotein lipase

Timepoint

baseline, endpoint

Method of measurement

ELISA

10**Description**

fasting induced adipose factor

Timepoint

baseline, endpoint

Method of measurement

ELISA

11**Description**

GLP1

Timepoint

baseline, endpoint

Method of measurement

ELISA

Intervention groups**1****Description**

Intervention group 1: herbal capsule manufactured by Dineh pharmaceutical company, Twice a day with hypocaloric diet (500 kcal less than patients' energy requirements), for 2 months

Category

Treatment - Drugs

2

Description

Intervention group 2: Metformin 500 mg manufactured by Glyonce, twice a day with hypocaloric diet (500 kcal less than patients' energy requirements), for 2 months

Category

Treatment - Drugs

3

Description

Control group: Placebo, twice a day with hypocaloric diet (500 kcal less than patients' energy requirements), for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Shirin Hasani-Ranjbar

Street address

Endocrinology and Metabolism Research Institute, 5th Floor, Shariati Hospital, North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411413137

Phone

+98 21 8822 0076

Email

sh_hasani@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development (NIMAD)

Full name of responsible person

Noncommunicable Disease Committee

Street address

No 21, Besat Ave., West Fatemi Ave.

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۶۹۳۱۱۱

Phone

+98 21 6693 8037

Email

NIMAD@RESEARCH.AC.IR

Grant name

Grant code / Reference number

942022

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

Yes

Title of funding source

National Institute for Medical Research Development (NIMAD)

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad-Reza Soroush

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Surgery

Street address

Endocrinology and Metabolism Research Institute, 5th Floor, Shariati Hospital, North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411413137

Phone

+98 21 8822 0076

Email

Soroush1344@gmail.com

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

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology

Street address

Endocrinology and Metabolism Research Institute, 5th Floor, Shariati Hospital, North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411413137

Phone

+98 21 8822 0076

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

هانیه السادات اجتهد

Position

PhD by research candidate

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Endocrinology and Metabolism Research Institute, 5th Floor, Shariati Hospital, North Kargar Ave.

City

Tehran

Province

Tehran

Postal code

1411413137

Phone

+98 21 8822 0076

Email

haniejtahed@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available