Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of moderately-restricted carbohydrate diet on intestinal microbiota and metabolic parameters in women with metabolic syndrome

Protocol summary

Study aim
The effect of moderately-restricted carbohydrate diet on intestinal microbiota and metabolic parameters in women with metabolic syndrome

Design
A clinical trial with a control group, with parallel groups, randomized on 70 patients

Settings and conduct
This study is a two-stage randomized clinical trial study that will be performed on adult women (20-50 years) with metabolic syndrome. The "invitation to participate in the research project" will be used in the Nutrition Clinic of Shariati Hospital, Tehran to reach the mentioned people. People will be randomly placed in a double block in terms of age and body mass index. The control group will be on a normal weight loss diet for 3 months, and the intervention group will be on a diet with moderate carbohydrate intake for 3 months.

Participants/Inclusion and exclusion criteria
Metabolic syndrome based on ATP III criteria, female gender, age 20-50 years, no menopause, overweight and obesity (BMI above 25), not pregnant and lactating, and willing to participate in the study. The study included: pregnancy at any stage of the study, smoking, chronic cardiovascular disease, liver, kidney disease, inflammatory bowel disease such as colitis, thyroid, diabetes, rheumatoid arthritis, cancer, lupus, severe infection, and trauma A history of weight loss surgery, a serious allergy to a particular drug or food, following a specific diet for the 3 months before the study, taking antibiotics and probiotic supplements over the past three months, and taking medications that affect weight.

Intervention groups
People in the intervention group will receive a weight loss diet with a limit of 500 kcal and a moderate carbohydrate intake limitation. People in the control group will receive a normal weight loss diet with a limit of 500 kcal.

Main outcome variables
Intestinal microbiome composition, components of metabolic syndrome

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210307050621N1**
Registration date: **2021-05-12, 1400/02/22**
Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**
Update count: **0**

Registration date
2021-05-12, 1400/02/22

Registrant information

Name
Seyed Mohammad Mousavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8895 5742

Email address
smmousavi1993@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of moderately-restricted carbohydrate diet on intestinal microbiota and metabolic parameters in women with metabolic syndrome

Public title
The effect of moderately-restricted carbohydrate diet on intestinal microbiota

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having metabolic syndrome based on The Adult Treatment Panel guidelines (ATP III) index Age 20 to 50 years Not being menopausal Body mass index greater than or equal to 25 Willingness to participate in the study
Exclusion criteria:
Pregnancy or breastfeeding or deciding to get pregnant shortly Smoking even one cigarette or once using other tobacco such as hookah in the past week or repeated drug use History of the liver, kidney, thyroid, gastrointestinal diseases, diabetes, rheumatoid arthritis, lupus, severe infection, and trauma History of weight loss surgery Having a serious allergy to a particular medicine or food Follow a special diet for 3 months before the study Take any amount of supplements or food products fortified with fins or probiotics during the last 3 months Taking a variety of antibiotics per dose during the 3 months before enrollment Taking drugs that affect weight, appetite, blood pressure, or metabolism of carbohydrates and fats in the last 3 months

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
First, subjects will be placed in double blocks in terms of age and body mass index. Then, randomly assigned individuals in each block will be assigned to intervention and control groups. To randomly assign individuals to groups, each person is assigned a code, and these codes are poured into a pot. An out-of-study person is then asked to draw the codes out of the pot using a lottery. The first code will be assigned to the intervention group, the second code to the control group, and so the rest of the people will be randomly assigned to the two groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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 Sciences

Street address
Faculty of Nutrition and Dietetics, University of Medical Sciences and Health Services, Tehran, Keshavarz Blvd., Naderi St., Hojjatdoost Alley, No. 44

City
Tehran

Province
Tehran

Postal code
1416643931

Approval date
2021-04-28, 1400/02/08

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.116

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Intestinal microbiome composition

Timepoint
Before the intervention and 3 months later

Method of measurement
Polymerase Chain Reaction (PCR) method

2

Description
Lipid profile (serum triglyceride, total serum cholesterol, low-density lipoprotein, high-density lipoprotein)

Timepoint
Before the intervention and 3 months later

Method of measurement
Enzymatic method

3

Description
Waist circumference
Timepoint
Before the intervention and 3 months later
Method of measurement
Tape meter

4

Description
Fasting blood sugar
Timepoint
Before the intervention and 3 months later
Method of measurement
By glucose oxidase method and using commercial kits

Secondary outcomes

1

Description
Body weight
Timepoint
Before the intervention and 3 months later
Method of measurement
Scale

2

Description
Blood pressure
Timepoint
Before the intervention and 3 months after the intervention
Method of measurement
Sphygmomanometer

3

Description
Height
Timepoint
Before the intervention and 3 months later
Method of measurement
Meter

Intervention groups

1

Description
Intervention group: Regular weight loss diet (daily limit of 500 kcal) and moderate carbohydrate restriction include 45-42% carbohydrates, 40-35% fat, and 17-15% protein. This diet should be consumed daily by participants for 3 months.
Category
Lifestyle

2

Description
Control group: The usual weight loss diet (daily limit of 500 kcal) includes 55-52% carbohydrates, 25-25% fat and 17-15% protein. This diet should be observed daily by participants for 3 months.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Using "Call to participate in a research project" in various places and in private offices in Tehran
Full name of responsible person
Dr Ahmad Esmaillzadeh
Street address
Faculty of Nutrition and Dietetics, No. 44, Hojjatdoost Alley, Naderi St., Keshavarz Blvd., Keshavarz Blvd., Tehran University of Medical Sciences and Health Services
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Faculty of Nutrition and Dietetics, No. 44, Hojjatdoost Alley, Naderi St., Keshavarz Blvd., Keshavarz Blvd., Tehran University of Medical Sciences and Health Services
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Info_snsd@tums.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
60
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
Seyed Mohammad Mousavi
Position
Ph.D Student
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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smmousavi@razi.tums.ac.ir

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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The study protocol will be written and published in the

form of an article. The clinical report of the study will be published in the form of an article.

When the data will become available and for how long

8 months after the end of the study

To whom data/document is available

The information will be made available to the public.

Under which criteria data/document could be used

To use the findings in the clinic or to write other articles, including review articles. In the case of original articles, researchers will be allowed to do so.

From where data/document is obtainable

Update information via email to the person in charge

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

After receiving the request from the person in charge of updating, the study will be provided to the researcher in consultation with the scientific officer.

Comments