

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Assessment and comparison of the effects of two types of low calorie low carbohydrate and low fat diets on intestinal microbiota changes and its association with some of metabolic factors alterations in obese women

#### Protocol summary

##### Study aim

Determination and comparison of the effect of low carbohydrate and low fat-low calorie diets on weight and waist circumference alterations in obese women  
Determination and comparison of the effect of low carbohydrate and low fat-low calorie diets on fasting lipid profile, blood sugar and insulin alterations in obese women  
Determination and comparison of the effect of low carbohydrate and low fat-low calorie diets on serum hs-CRP alterations in obese women  
Determination and comparison of the effect of low carbohydrate and low fat-low calorie diets on intestinal microbiota alterations in obese women

##### Design

Cross-over clinical trial, single blinded, randomized which is randomly assigned to 2 groups receiving low calorie-low fat and low carbohydrate diets.

##### Settings and conduct

obese women attending to the nutrition clinic receive low fat or low carbohydrate diet for 6 weeks, then 2 weeks washout and then exchange the diet groups again for 6 weeks.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: body mass index higher than 30, age between 18-50 years, female  
exclusion criteria: antibiotic intake now/or at least at the one month ago, intake of probiotic supplements at least at the 3 month ago or during the study period, pregnancy and lactation, menopause, liver, kidney, cardiac diseases, gastrointestinal diseases and malabsorption, type 1 and 2 diabetes, cancer, hypothyroidism, special diets, alcohol intake or smoking, participants with compliance lower than 80%, vigorous exercise

##### Intervention groups

low fat diet group low carbohydrate diet group

##### Main outcome variables

weight, waist circumference, fasting lipid profile, fasting blood sugar and insulin, high sensitive C-reactive protein,

intestinal microbiota

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200929048876N3**

Registration date: **2021-01-08, 1399/10/19**

Registration timing: **prospective**

Last update: **2021-01-08, 1399/10/19**

Update count: **0**

##### Registration date

2021-01-08, 1399/10/19

##### Registrant information

##### Name

Seyedeh Neda Mousavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3315 6300

##### Email address

neda.mousavi@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-09, 1399/10/20

##### Expected recruitment end date

2021-06-22, 1400/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Assessment and comparison of the effects of two types of low calorie low carbohydrate and low fat diets on intestinal microbiota changes and its association with some of metabolic factors alterations in obese women

## Public title

Diet and intestinal microbiota alterations

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Body mass index equal or higher than 30 female ages of 18 to 50 year

### Exclusion criteria:

## Age

From **18 years** old to **50 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Blocked randomization will be used as two groups with 4-number blocks including 5 participant in each group. randomization unit is person and we will use random allocation software for this purpose. random coded boxes will be used for concealment. At this method, cans with similar weight, shape and color which are numbered according to the random sequence will be used.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Zanjan University of Medical Sciences

##### Street address

Azadi Blv, Zanjan University of Medical Sciences

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956184

##### Approval date

2021-01-06, 1399/10/17

##### Ethics committee reference number

IR.ZUMS.REC.1399.350

## Health conditions studied

### 1

#### Description of health condition studied

Obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

## Primary outcomes

### 1

#### Description

weight alterations

#### Timepoint

baseline and after 6 weeks

#### Method of measurement

scale

### 2

#### Description

fasting blood sugar alterations

#### Timepoint

baseline and after 6 weeks

#### Method of measurement

autoanalyzer setting

### 3

#### Description

fasting triglyceride alterations

#### Timepoint

baseline and after 6 weeks

#### Method of measurement

autoanalyzer setting

### 4

#### Description

total cholesterol alterations

#### Timepoint

baseline and after 6 weeks

#### Method of measurement

autoanalyzer setting

### 5

#### Description

LDL.C cholesterol alterations  
**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
autoanalyzer setting

## 6

**Description**  
HDL.C cholesterol alterations  
**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
autoanalyzer setting

## 7

**Description**  
Waist circumference alterations  
**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
centimeter

## 8

**Description**  
intestinal microbiota alterations  
**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
autoanalyzer setting

## 9

**Description**  
blood pressure alterations  
**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
autoanalyzer setting

## 10

**Description**  
C-reactive protein alterations  
**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
ELIZA kit

## 11

**Description**  
serum insulin alterations  
**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
ELIZA kit

## 12

**Description**  
hip circumference alterations

**Timepoint**  
baseline and after 6 weeks  
**Method of measurement**  
centimeter

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

**Description**  
Intervention and control group: From the total daily calorie needs, 500 kcal per day will be reduce for 0.5 kg weight reduction in each patient. In low fat diet 20% of total daily calorie will receive from fat (with emphasis on mono and poly- unsaturated plant fatty acids), 15% from protein and 65% from carbohydrates.

**Category**  
Lifestyle

### 2

**Description**  
Control and intervention group: From the total daily calorie needs, 500 kcal per day will be reduce for 0.5 kg weight reduction in each patient. In low carbohydrate diet 20% of total daily calorie will receive from carbohydrate, 25% from protein and 55% from fats (with emphasis on mono and poly- unsaturated plant fatty acids).

**Category**  
Lifestyle

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shafieieh Clinic

##### **Full name of responsible person**

Dr. Hossein Chiti

##### **Street address**

Shariati St

##### **City**

Zanjan

##### **Province**

Zanjan

##### **Postal code**

4513956184

##### **Phone**

+98 24 3315 6300

##### **Email**

dr.chiti@zums.ac.ir

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Shoghli

**Street address**

Azadi Blv.

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956184

**Phone**

+98 24 3315 6400

**Email**

shoghli@zums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Mahnaz Karbalaee

**Position**

fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Valie-Asr Hospital, Shariati St

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956184

**Phone**

+98 24 3315 6300

**Email**

karbalaee.mahnaz@yahoo.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr.Seyedeh Neda Mousavi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Mahdavi Blv., 13th St.

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956184

**Phone**

+98 24 3315 6300

**Email**

neda.mousavi@zums.ac.ir

### Person responsible for updating data

**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr. Seyedeh Neda Mousavi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Mahdavi Blv., 13th St.

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956184

**Phone**

+98 24 3315 6300

**Email**

neda.mousavi@zums.ac.ir

### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

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**

Yes - There is 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

**Title and more details about the data/document**

without participant name

**When the data will become available and for how long**

After study final

**To whom data/document is available**

All person

**Under which criteria data/document could be used**

All person

**From where data/document is obtainable**

Zanjan University of Medical Sciences, Deputy of Research and Thechnology

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

straight referee to Deputy of Research and Technology of Zanjan University of Medical Sciences

**Comments**