Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluating the efficacy of low-carbohydrate (Paleo diet) and moderate-carbohydrate diet with two delivery mode; “fixed diet plan” vs “calorie counting” on body composition, serum levels of some hepatokines and adipocytokines and flowcytometric analysis of endothelial micro particles (EMPs) in adults with metabolic syndrome: A randomized clinical trial

Protocol summary

Summary

Objectives: Patients with metabolic syndrome will be assessed to determine the effects of low carbohydrate diets on serum concentrations of inflammatory and metabolic factors, weight and body composition. Design: A randomized controlled trial with factorial design. Setting and conduct: 80 Subjects will be randomly divided into four groups. For each patient anthropometric measurement, general characteristics will be assessed and 15 cc fasting blood samples will be taken from each patient at the baseline and end of study. 24-h food record questionnaire and physical activity questionnaire will be completed every four week. Inclusion criteria: Age: 20-50 years old; meeting the NCEP-ATPIII criteria (Three or more of the following five criteria should be met: Waist circumference over 40 inches (men) or 35 inches (women); Blood pressure over 130/85 mmHg; Fasting triglyceride over 150 mg/dl; Fasting HDL-cholesterol less than 40 mg/dl (men) or 50 mg/dl (women) and fasting blood sugar over 100 mg/dl). Exclusion criteria: Alcohol and tobacco consumption; Pregnancy; Lactation, Menopause; History of acute or chronic liver failure; Gastrointestinal diseases; Cholestasis; Diabetes, Kidney disease, Seizure, Autoimmune diseases, Thyroid disorders; Using estrogen, Hormone replacement therapy; Routine consumption of oral contraceptives, Insulin therapy; Malignancy; Routine consumption of antioxidants and vitamin/mineral supplements; Following vegetarian diet or any other special diet in the last 3 months. Intervention: Subjects will randomly receive either type of low carbohydrate diets for 12 weeks. Main outcome measures (variables): Weight changes, Body composition, Serum CTRP1, FGF-21, Chemerin, Asprosin, plasma levels of EMPs, Appetite regulatory hormones before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121925267N4**
Registration date: **2017-07-26, 1396/05/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-26, 1396/05/04

Registrant information

Name
Maryam Mahmoudi
Name of organization / entity
School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences,
Country
Iran (Islamic Republic of)
Phone
+98 21 8895 5975
Email address
m-mahmoudi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of low-carbohydrate (Paleo diet) and moderate-carbohydrate diet with two delivery mode; “fixed diet plan” vs “calorie counting” on body composition, serum levels of some hepatokines and adipocytokines and flowcytometric analysis of endothelial micro particles (EMPs) in adults with metabolic syndrome: A randomized clinical trial

Public title

Evaluating the efficacy of two types of low-carbohydrate diets on weight, metabolic and inflammatory factors in patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria consists of: Age between 20 and 50 years old; Diagnosis of metabolic syndrome according to the NCEP-ATPIII criteria (If three or more of the following five criteria are met: Waist circumference over 40 inches (men) or 35 inches (women); Blood pressure over 130/85 mmHg; Fasting triglyceride (TG) level over 150 mg/dl; Fasting high-density lipoprotein (HDL) cholesterol level less than 40 mg/dl (men) or 50 mg/dl (women) and fasting blood sugar over 100 mg/dl). Exclusion criteria are: Alcohol and tobacco consumption; Pregnancy; Lactation; Menopause; History of acute or chronic liver failure; Acute or chronic gastrointestinal diseases, Cholestasis; Diabetes, Kidney disease, Seizure, Autoimmune diseases, Thyroid disorders; Using hormonal drugs such as estrogen, Hormone replacement therapy, Routine consumption of oral contraceptives, Insulin therapy; Malignancy or neoplasia; Routine consumption of antioxidants and vitamin/mineral supplements; Following vegetarian diet or any other special diet in the last 3 months.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Balanced Block Randomization

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Qods St, Keshavarz blv, Tehran, Iran.

City

Tehran

Postal code

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2046

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Weight

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Scale

2

Description

Body Composition

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Body Impedence Analysis

3

Description

Serum Asprosin

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELISA assay

4

Description

Serum Chemerin

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELISA assay

5

Description

FGF-21

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELISA assay

6

Description

Serum CTRP1

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELISA assay

7

Description

Plasma level of Endothelial Microparticles (CD 31,105, 146)

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Flowcytometry

8

Description

Appetite regulatory hormones (Peptide YY and ghrelin)

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELISA assay

Secondary outcomes

1

Description

Lipid profiles (TC, TG, LDL-C, HDL-C)

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Enzymatic methods for TC,TG and HDL-C For LDL-C : Freidwald's formula: LDL-C = TC- HDL-C - (TG/5)

2

Description

Fasting blood glucose

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Enzymatic colorimetric

3

Description

Fasting insulin serum

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

ELISA assay

4

Description

Insulin resistance

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

HOMA-IR calculation

5

Description

Insulin sensitivity

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

QUICKI calculation

6

Description

Urine Sodium

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

Electrolyte Analyzer

7

Description

Urine Potassium

Timepoint

Baseline and 12 weeks after intervention

Method of measurement
Electrolyte Analyzer

8

Description
HS-CRP
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

9

Description
Appetite changes
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
VAS questionnaire

10

Description
Leptin
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
ELISA assay

11

Description
Creatinine
Timepoint
Baseline and 12 weeks after intervention
Method of measurement
Spectrophotometer

Intervention groups

1

Description
Intervention group 4: Receiving moderate carbohydrate diet with “fixed diet plan” for 12 weeks. Medium-carbohydrate diet is defined as a 40% carbohydrate, 30% protein and 30% fat diet.
Category
Lifestyle

2

Description
Intervention group 3: Receiving moderate carbohydrate diet with calorie counting for 12 weeks. Medium-carbohydrate diet is defined as a 40% carbohydrate, 30% protein and 30% fat diet.
Category
Lifestyle

3

Description
Intervention group 1: Receiving paleo diet with calorie counting for 12 weeks. Low-carbohydrate paleo diet is defined as a 20% carbohydrate, 35% protein and 45% fat diet.
Category
Lifestyle

4

Description
Intervention group 2: Receiving paleo diet with “fixed diet plan” for 12 weeks. Low-carbohydrate paleo diet is defined as a 20% carbohydrate, 35% protein and 45% fat diet.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes and Metabolic diseases Clinic; Municipal Districts of Tehran
Full name of responsible person
Ms.Shariat
Street address
Building of Social and Cultural Affairs, Intersection of the Gomnam Shahid Autobahn, Kurdistan highway, Tehran, Iran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Dr.Masud Yunesian
Street address
Qods St, Keshavarz blv, Tehran, Iran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Maryam Mahmoudi

Position

MD and PhD in Nutritional Sciences, Associate Professor

Other areas of specialty/work

Street address

No. 44, Hojatdoost Alley, Naderi St, Keshavarz blv, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 8895 5569

Fax

Email

m-mahmoudi@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Maryam Mahmoudi

Position

MD and PhD in Nutritional Sciences, Associate Professor

Other areas of specialty/work

Street address

No. 44, Hojatdoost Alley, Naderi St, Keshavarz blv, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 8895 5569

Fax

Email

m-mahmoudi@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farnosh Shemirani

Position

PhD student in Nutrition Sciences

Other areas of specialty/work

Street address

No. 44, Hojatdoost Alley, Naderi St, Keshavarz blv, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 8895 5569

Fax

Email

sfarnosh@yahoo.com; jfaranush@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty