

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

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Name of organization / entity

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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 Impedance 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
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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