

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative effects of moderate carbohydrate restriction vs. high-carbohydrate diet on serum levels of adipocytokines, inflammatory indices and biomarkers of endothelial function among women with metabolic syndrome

Protocol summary

Summary

This cross-over randomized clinical trial aims to determine the effect of moderately-restricted dietary carbohydrate and its replacement with fats on serum levels of adipocytokines, inflammatory indices and biomarkers of endothelial function among 40 women with metabolic syndrome aged 20-65 y. Non-pregnant and non-lactating women with body mass index greater than 25 that have not affected by gastrointestinal, renal, liver and thyroid disorders, diabetes, rheumatoid arthritis, Lupus, severe infection, trauma, surgery and allergy and also have not used medications that would affect carbohydrate and fat metabolism, blood pressure and inflammations during 3 mo ago will be included in this study. This study would compare the effect of usual Iranian diet (60-65% of energy from carbohydrates, 20-25% from fats and 15-17% from proteins) with that of moderately-restricted carbohydrate diet (43-47% of energy from carbohydrates, 36-40% from fats and 15-17% from proteins) on serum adipocytokine levels in a cross-over design. In this study, participants would have a 2-week run-in period, followed by a 6-week intervention and then a 2-week washout period followed by the second phase of a 6-week intervention period. Anthropometric measures, body composition, blood pressure, biochemical measures including fasting plasma glucose, serum insulin, triglyceride, total-cholesterol, high density lipoprotein cholesterol (HDL-c), and low density lipoprotein cholesterol (LDL-c), blood urea nitrogen (BUN), creatinin, E-selectin, high sensitivity C-reactive protein (hs CRP), high sensitive interleukin 6 (hs IL-6), high sensitive tumor necrosis factor-alpha (hs TNF- α), serum amyloid A (SAA), serum inter-cellular adhesion molecule (sICAM-1), serum vascular cell adhesion molecule (sVCAM-1), leptin and adiponectin levels would be measured at the beginning and end of phase I and II.

To assess the compliance of the participants, we will assess dietary intakes of subjects by the use of dietary records once in every two weeks. Physical activity levels will also be assessed by a physical activity record once in every two weeks. Appropriate statistical methods will be applied for data analyses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105131485N3**

Registration date: **2011-06-11, 1390/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-11, 1390/03/21

Registrant information

Name

Ahmad Esmailzadeh

Name of organization / entity

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Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of
Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effects of moderate carbohydrate restriction vs. high-carbohydrate diet on serum levels of adipocytokines, inflammatory indices and biomarkers of endothelial function among women with metabolic syndrome

Public title

The effect of low-carbohydrate diet on inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being non-pregnant and non-lactating women; aged 20-65 y; having metabolic syndrome according to Adult Treatment Panel III definition; body mass index greater than 25 kg/m²; non-smokers; and lack of gastrointestinal, renal, liver and thyroid disorders; lack of diabetes, rheumatoid arthritis, Lupus; severe infection and trauma; surgery and allergy; lack of adherence to a specific diet and the use of medications in the last 3 months; having dietary carbohydrate intake between 35%-65% of total energy. Exclusion criteria: Pregnancy at any stage of the study; severe infection; trauma; surgery; allergy; alterations in physical activity and supplement use; lack of adherence to the prescribed diets.

AgeFrom **20 years** old to **65 years** old**Gender**

Female

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description**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**

Ethical Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Ave, Isfahan

City

Isfahan

Postal code

8174673461

Approval date

2010-08-09, 1389/05/18

Ethics committee reference number

189047

Health conditions studied**1****Description of health condition studied**

Metabolic Syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

serum high sensitive-C Reactive Protein (hs-CRP) levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

high sensitive immunoturbidimetry, mg/dL

2**Description**

serum high sensitive tumor necrosis factor-alpha (hs TNF-α) levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) .mg/dL

3**Description**

serum high sensitive Interleukin 6 (hs IL-6) levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) .ng/dL

4**Description**

Serum Amyloid A (SAA) levels
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA) ,mg/dL

5

Description
serum E-selectin levels
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA) ,ng/dL

6

Description
serum Inter-Cellular Adhesion Molecule 1 (sICAM-1) levels
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA) ,µg/L

7

Description
serum vascular cell adhesion molecule 1 (sVCAM-1) levels
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA) ,µg/L

8

Description
serum leptin levels
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA) ,ng/mL

9

Description
serum adiponectin levels
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
Enzyme-Linked Immunosorbent Assay (ELISA) ,µg/mL

Secondary outcomes

1

Description
Weight
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
scale, kilogram

2

Description
Waist circumference
Timepoint
Baseline, Week 2, Week 8, Week 10, Week 16
Method of measurement
meter, centimeter

3

Description
hip circumference
Timepoint
baseline, week 2, week8, week 10, week 16
Method of measurement
centimeter, meter

4

Description
body mass index
Timepoint
Baseline, Week 2, Week 8, Week 10, Week 16
Method of measurement
kg/m2, Weight/Height square

5

Description
fat mass
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
percent, Bioelectrical Impedance Analysis method

6

Description
fat free mass
Timepoint
Week 2, Week 8, Week 10, Week 16
Method of measurement
percent, Bioelectrical Impedance Analysis method

7

Description
systolic blood pressure
Timepoint
Baseline, Week 2, Week 8, Week 10, Week 16
Method of measurement
mmHg, digital sphygmomanometer

8

Description
diastolic blood pressure
Timepoint
Baseline, Week 2, Week 8, Week 10, Week 16
Method of measurement
mmHg, digital sphygmomanometer

9

Description

fasting blood sugar

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

mg/dL, Colorimetric

10

Description

serum insulin levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA), μ U/mL

11

Description

serum Triglyceride levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

photometrics, mg/dL

12

Description

serum total cholesterol levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

photometrics, mg/dL

13

Description

serum Low-Density Lipoprotein cholesterol (LDL-c) levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

Enzymatic, mg/dL

14

Description

serum High-Density Lipoprotein cholesterol (HDL-c) levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

photometrics, mg/dL

15

Description

serum Blood Urea Nitrogen (BUN) levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

photometrics, mg/dL

16

Description

Serum creatinine levels

Timepoint

Week 2, Week 8, Week 10, Week 16

Method of measurement

photometrics, mg/dL

Intervention groups

1

Description

Moderately carbohydrate-restricted diet: carbohydrate 43-47%; fat 36-40%, protein 15-17% 15-20% reduction in energy from carbohydrate will be replaced by non-hydrogenated vegetable oils. All participants follow this diet for 6 weeks.

Category

Lifestyle

2

Description

Usual Iranian diet: carbohydrate 60-65%; fat 20-25%, protein 15-17% All participants follow this diet for 6 weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Isfahan Oil Industry

Full name of responsible person

Somayeh Rajaie

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Adibi

Street address

Hezar Jerib Ave, Isfahan

City

Isfahan

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, Isfahan 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
Isfahan University of Medical Sciences

Full name of responsible person
Ahmad Esmailzadeh

Position
PhD

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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