Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 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 it's 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, sever 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 Esmaillzadeh

Name of organization / entity
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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; sever 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; sever infection; trauma; surgery; allergy; alterations in physical activity and supplement use; lack of adherence to the prescribed diets.
Age
From **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),µU/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 Esmaillzadeh

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