

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparative effects of high versus low energy-dense diets on serum levels of adipokines and inflammatory biomarkers in type 2 diabetic women

Protocol summary

Summary

This randomized parallel clinical trial will be performed among overweight or obese ($BMI > 25 \text{ kg/m}^2$) type 2 diabetic women aged 30-60 y. Individuals with the use of medications affecting inflammatory biomarkers and adipocytokines and also those with the chronic conditions affecting these biomarkers would not be included in the study. At baseline, we would have a 2-week run-in period for all participants. During this period, 3-day diet records as well as 3-day physical activity records would be collected. Then, after matching for age, BMI, current medication use and menopausal status, participants will be randomly assigned to consume low-energy dense diet, high-energy dense diet or usual diabetes meal plan for 8 weeks. Biochemical indicators (Fasting plasma glucose, serum insulin levels, serum lipid profiles, serum levels of hs-CRP, hs-TNF- α , hs-IL-6, Adiponectin, Visfatin and Chemerin) as well as anthropometric measures will be assessed at baseline and after 8 weeks. Low-energy dense diet would be a weight loss diet (-500kcal) containing 50-60% of energy from carbohydrates, 25% from fats and 15-20% from proteins. Individuals adhering to this diet would have higher intakes of fruits, vegetables and beverages and lower intakes of dietary fat. High-energy dense diet would be a weight loss diet (-500kcal) containing 45-50% of energy from carbohydrates, 35% from fats and 15-20% from proteins. Individuals adhering to this diet would have lower intakes of fruits and vegetables and higher intakes of dietary fat. Usual Diabetes meal plan would be a conventional weight loss diet (-500 kcal) containing 50-55% of energy from carbohydrates, 30% from fat and 15-20% from proteins. To assess compliance, participants will be asked to obtain a 24-hour dietary recall once in a 2 weeks during the study period. Also, they will be asked to obtain three daily physical activity records during this period. All

biochemical measures and anthropometric assessments will be done at the end of trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105281485N4**

Registration date: **2011-06-13, 1390/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-13, 1390/03/23

Registrant information

Name

Ahmad Esmailzadeh

Name of organization / entity

Department of Nutrition, School of Public Health,
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

2010-11-22, 1389/09/01

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 high versus low energy-dense diets on serum levels of adipokines and inflammatory biomarkers in type 2 diabetic women

Public title

Dietary energy density and type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic non-pregnant and non-lactating females aged 30-60 y, Lack of insulin injection, non-smokers, lack of having a special diet except for usual diabetes meal plan, lack of severe weight loss in the last 3 months, not having severe infection in the last 3 months, trauma, surgery, hypo- and hyper-thyroidism, lack of the use of vasodilators, antioxidant supplements, vitamin and mineral supplements, diuretics, betablockers, garlic, OCP, aspirin and corticosteroids. Exclusion criteria: Lack of adherence to the prescribed diet, starting the use of above-mentioned medications or affecting by the above-mentioned diseases, alterations in dosage and type of current medications, getting pregnant

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethical committee of isfahan university of medical science

Street address

Isfahan University of Medical Sciences, Hezar Jerib Ave, Isfahan

City

isfahan

Postal code

8174673461

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

189106

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

diabetes

ICD-10 code

E11

ICD-10 code description

دیابت نوع 2 ، چاق، بزرگسالان، بالغین، غیر کتونیک، پایدار، نوع 2

Primary outcomes**1****Description**

serum visfatin level

Timepoint

before the intervention week 8

Method of measurement

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

2**Description**

serum adiponectin level

Timepoint

before the intervention week 8

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) ,ug/dL

3**Description**

serum chemerin level

Timepoint

before the intervention week 8

Method of measurement

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

4**Description**

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

Timepoint

before intervention and week 8

Method of measurement

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

5

Description

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

Timepoint

before intervention and week 8

Method of measurement

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

6

Description

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

Timepoint

before the intervention week 8

Method of measurement

high sensitive immunoturbidimetry, mg/dL

Secondary outcomes

1

Description

hip circumference

Timepoint

before the intervention week 8

Method of measurement

centimeter, meter

2

Description

body mass index

Timepoint

before the intervention week 8

Method of measurement

kg/m², Weight/Height square

3

Description

Waist circumference

Timepoint

before the intervention week 8

Method of measurement

meter, centimeter

4

Description

Weight

Timepoint

before the intervention week 8

Method of measurement

scale, kilogram

5

Description

fasting blood sugar

Timepoint

before the intervention week 8

Method of measurement

mg/dL, Colorimetric

6

Description

serum insulin levels

Timepoint

before the intervention week 8

Method of measurement

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

7

Description

serum Triglyceride levels

Timepoint

before the intervention week 8

Method of measurement

photometrics, mg/dL

8

Description

serum total cholesterol levels

Timepoint

before the intervention week 8

Method of measurement

photometrics, mg/dL

9

Description

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

Timepoint

before the intervention week 8

Method of measurement

Enzymatic, mg/dL

10

Description

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

Timepoint

before the intervention week 8

Method of measurement

photometrics, mg/dL

Intervention groups

1

Description

High-energy dense diet : High-energy dense diet would be a weight loss diet (-500kcal) diet. this diet containing 45-50% of energy from carbohydrates, 35% from fats and 15-20% from proteins. Individuals adhering to this diet would have lower intakes of fruits and vegetables and higher intakes of dietary fat.

Category

Treatment - Other

2

Description

low energy dense diet: Low-energy dense diet would be a weight loss diet (-500kcal)diet.this diet containing 50-60% of energy from carbohydrates, 25% from fats and 15-20% from proteins. Individuals adhering to this diet would have higher intakes of fruits, vegetables and beverages and lower intakes of dietary fat.

Category

Treatment - Other

3

Description

normal diet:normal diet would be a weight loss diet (-500kcal)diet.this diet containing 50-55% of energy from carbohydrates, 30% from fats and 15-20% from proteins.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

health centres of Isfahan university of medical science

Full name of responsible person

Maryam Tabesh

Street address

Isfahan University of Medical Sciences, Hezar Jerib Ave, Isfahan

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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

Isfahan University of Medical Sciences, 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**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