Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the effect of low-carbohydrate compared with low-fat diet on metabolic profiles in type 2 diabetes patients with coronary heart disease

Protocol summary

Study aim

The aim of this study is to determine the effects of carbohydrate versus fat restriction on metabolic profiles among type 2 diabetes patients with coronary heart disease (CHD).

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: 56 type 2 diabetes patients with CHD eligible and referred to Cardiology Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Overweight patients aged 40-85 years old and diagnosed with type 2 diabetes and coronary heart disease. Exclusion Criteria: Consuming antiobesity medications within the last 3 months, having an acute myocardial infarction and cardiac surgery within the last 3 months, renal or liver failure.

Intervention groups

Intervention: Patients will be assigned to receive either carbohydrate restriction (n=28) or fat restriction (n=28). Fasting blood samples will be taken at baseline and after 8-wk intervention to measure metabolic profiles. Start and end date of intervention: 8 weeks.

Main outcome variables

Outcomes: Biomarkers of insulin metabolism (primary outcomes), and lipid and metabolic profiles (secondry outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201601025623N61**
Registration date: **2016-01-09, 1394/10/19**
Registration timing: **retrospective**

Last update: **2019-11-10, 1398/08/19**
Update count: **1**

Registration date

2016-01-09, 1394/10/19

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 36 1534 3570

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-11-01, 1394/08/10

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of low-carbohydrate compared with low-fat diet on metabolic profiles in type 2 diabetes patients with coronary heart disease

Public title

Effect of diet therapy in treatment of Coronary Heart Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Overweight patients aged 40-85 years old Diagnosed with type 2 diabetes and coronary heart disease

Exclusion criteria:

Consuming antiobesity medications within the last 3 months Having an acute myocardial infarction and cardiac surgery within the last 3 months Renal or liver failure

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to receive either carbohydrate restriction (n = 28) or fat restriction (n = 28). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Approval date

2015-11-01, 1394/08/10

Ethics committee reference number

IR.Kaums.REC.1394.96

Health conditions studied

1

Description of health condition studied

Coronary Heart Disease

ICD-10 code

I25.9

ICD-10 code description

Ischaemic heart disease (chronic) NOS

Primary outcomes

1

Description

Insulin

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

hs-CRP

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa kit

2

Description

Triglycerides

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

Total antioxidant

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Glutathione

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

7

Description

Nitric oxide

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

8

Description

VLDL

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

9

Description

LDL

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

10

Description

FPG

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

11

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Carbohydrates restriction group: 43-47% carbohydrates, 36-40% fats, for 8 weeks.

Category

Other

2

Description

Fats restriction group: 60-65% carbohydrates, 20-25% fats, for 8 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Cardiology Clinic

Full name of responsible person
Zatollah Asemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person
Gholamali Hamidi

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research@kaums.ac.ir

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, Kashan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Zatollah Asemi

Position
Nutrition PhD

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available