Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of folate supplementation on on carotid intima media thickness (CIMT) and metabolic profiles among type 2 diabetes patients with coronary heart disease

Protocol summary

Study aim

The aim of this study is to determine the effects of folate supplementation on carotid intima media thickness (CIMT), metabolic profiles, inflammatory factors and biomarkers of oxidative stress among type 2 diabetes patients with coronary heart disease (CHD).

Design

Study design: Parallel double-blind randomized controlled clinical trial.

Settings and conduct

Population and sample size: 60 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: Invituals aged 40-85 years diagnosed with type 2 diabetes and CHD will be included in this study. Exclusion criteria: Intake of folate supplements within the last 3 months, acute myocardial infarction within the past 3 months, cardiac surgery within the past 3 months, renal or liver failure.

Intervention groups

Intervention: Patients will be assigned to receive either 5 mg/day folate supplements (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Outcomes: Biomarkers of insulin metabolism (primary outcome) and glucose homeostasis parameters, lipid profiles, biomarkers of inflammation and oxidative stress (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: **IRCT201503175623N40**
Registration date: **2015-03-28, 1394/01/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**
Update count: **1**

Registration date

2015-03-28, 1394/01/08

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

Kashan University of Medical Sciences

Expected recruitment start date

2015-03-06, 1393/12/15

Expected recruitment end date

2015-04-03, 1394/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of folate supplementation on on carotid intima media thickness (CIMT) and metabolic profiles among type 2 diabetes patients with coronary heart disease

Public title
Effect of supplementation in treatment of Coronary Heart Disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Subjects aged 40-85 years Diagnosed with type 2 diabetes and CVD

Exclusion criteria:
Intake of folate supplements within the last 3 months Acute myocardial infarction within the past 3 months Cardiac surgery within the past 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: **60**

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 take folate supplements (n = 30) or placebo (n = 30). 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.Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kashan University of Medical Sciences

Street address
Bolvare Ghotbe Ravandi, Kashan

City
Kashan

Province
Isfehan

Postal code
81151-87159

Approval date
2015-03-05, 1393/12/14

Ethics committee reference number
5751

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
Carotid intima media thickness

Timepoint
Baseline and End-of-trial

Method of measurement
Sonography

Secondary outcomes

1

Description
Fasting plasma glucose

Timepoint
Baseline and End-of-trial

Method of measurement
Enzymatic

2

Description
Insulin

Timepoint

Baseline and End-of-trial
Method of measurement
Elisa

3

Description
Cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

4

Description
Triglyceride
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

5

Description
Insulin resistance
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa kit

6

Description
HDL-cholesterol
Timepoint
Baseline and End-of-trial
Method of measurement
Enzymatic

7

Description
Hs-CRP
Timepoint
Baseline and End-of-trial
Method of measurement
Elisa kit

8

Description
Nitric oxide
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

9

Description
Malondialdehyde
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

10

Description
Glutathione
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

11

Description
Total antioxidant capacity
Timepoint
Baseline and End-of-trial
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Intervention group: Folate tablet, 5 mg, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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