Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 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)

Phone
+98 36 1534 3570

Email address
asemi_z@kaums.ac.ir

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

City

Kashan

Province

Isfehan

Postal code

81151-87159

Phone

+98 31 5546 3378

Email

asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Street address
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5554 2999
Email
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
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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

Person responsible for scientific 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
Street address
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for updating data

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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

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