

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effects of vitamin C supplementation on LCAT (lecithin-cholesterol Acyltransferase) activity compared to placebo in patients with type 2 diabetes

Protocol summary

Study aim

Investigate of effects of vitamin C supplementation on LCAT activity level in patients with type 2 diabetes in diabetic clinic of Imam khomeini hospital

Design

Randomized double blind clinical trial ,with 60 sample size.

Settings and conduct

This study will be conducted in diabetes clinic of imam Khomeini hospital in Tehran university of medical sciences. All diabetic patients enrolled in the study according to inclusion criteria. Informed consent will be taken of the patients, then demographic and anthropometric data will be registered, and primary lab data will be taken from the patients. Then the patients Randomized in two groups. Group 1 :will be received vitamin c 500 mg daily for 2 month, group 2: will be received placebo as group 1 for 2 months After 2 months ,blood samples will be taken from both groups and lab data and LCAT activity will be measured and analyzed .

Participants/Inclusion and exclusion criteria

Inclusion criteria: type 2 diabetes,age more than 30 year.
Exclusion criteria : pregnancy,vitamin use,glucocorticoid use,renal failure,heart failure ,smoker,liver failure,malignancy,acute inflammation and infections, hypersensitivity to vitamin c ,antioxidant drug use ,hypothyroidism, renal stone.

Intervention groups

Prescription vitamin c and placebo randomly in two groups.

Main outcome variables

LCAT level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160811029306N2**

Registration date: **2020-11-11, 1399/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-11, 1399/08/21**

Update count: **0**

Registration date

2020-11-11, 1399/08/21

Registrant information

Name

Manouchehr Nakhjavani

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 6694 8671

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-05, 1399/08/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of vitamin C supplementation on

LCAT (lecithin-cholesterol Acyltransferas) activity compared to placebo in patients with type 2 diabetes

Public title

vitamin c in diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Type2 diabetes More than 2 years history of type2 diabetes

Exclusion criteria:

pregnancy vitamin supplementation glucocorticoid use renal failure history of heart failure smoking liver failure malignancy acute inflammation and infection antioxidant drugs allergy to vitamin c hypothyroidism renal stone

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed via random allocation software and patients will be categorized into vitamin c user and placebo user.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. Both participants and investigator are blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam Khomeini hospital complex, tehran University of Medical Sciences

Street address

No 20, keshavarz Blvd ,Imam khomeini hospital

City

Tehran

Province

Tehran

Postal code

1419733147

Approval date

2020-10-14, 1399/07/23

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.263

Health conditions studied

1

Description of health condition studied

type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

LCAT(lecithin-cholesterol Acyltransferas)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

LCAT will be measured by spectrophotometric assay

2

Description

HbA1c

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

Hb A1C will be measured by electrophoresis

3

Description

High Density Cholesterol (HDL)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

HDL will be measured by Direct Enzymatic.

4

Description

Low Density Cholesterol (LDL)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

LDL will be measured by Direct Enzymatic

5

Description

Insulin

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

Insulin will be measured by Chemiluminescence immunoassay.

6

Description

triglyceride (TG)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

TG will be measured by enzymatic (GPO-POD) method.

7

Description

Fasting Blood Glucose (FBS)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

FBS will be measured by enzymatic (GOD) method.

8

Description

Creatinine (Cr)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

Cr will be measured by photometric method.(PICRATE/KINETIC)

9

Description

Aspartate transaminase (AST)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

AST will be measured by enzymatic method.

10

Description

Alanine transaminase (ALT)

Timepoint

Blood sample will be taken before and 2 months after treatment with vitamin c .

Method of measurement

ALT will be measured by enzymatic method.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral vitamin c supplement

Category

Prevention

2

Description

Control group: Placebo

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic of Imam khomeini hospital

Full name of responsible person

manouchehr nakhjavani

Street address

No 20, keshavarz Blvd ,Imam khomeini hospital complex ,Diabetes Clinic.

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+98 21 6119 1294

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nakhjavanim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice Chancellor for medical sciences

Street address

Keshavarz Blvd , Qods Town

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email
vcr@tums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
manouchehr nakhjavani

Position
Endocrinology and metabolism

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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No 20, keshavarz Blvd ,Imam khomeini hospital
compelx ,Vali asr hospital

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Contact

Name of organization / entity
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manouchehr nakhjavani

Position
Endocrinology and metabolism

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Latest degree
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Other areas of specialty/work
Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

patients data is confident, I don't intend to publish the participants information file.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available