

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of effects of vitamin C supplementation on LCAT (lecithin-cholesterol Acyltransferas) 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 anthropocentric 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)

##### Phone

+98 21 6694 8671

##### Email address

nakhjavanim@tums.ac.ir

#### 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.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1419733147

##### **Phone**

+98 21 6119 1294

##### **Email**

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

**Street address**

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

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**Email**

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**Person responsible for scientific 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

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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endocrinology and metabolism

**Latest degree**

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**Other areas of specialty/work**

Internal Medicine

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No 21,Vali asr hospital, keshavarz Bolvd, tehran ,Iran

**City**

tehran

**Province**

Tehran

**Postal code**

1419733147

**Phone**

+98 21 61190

**Email**

nakhjavanim@tums.ac.ir

**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