

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effects of ascorbic acid on AGEs, AOPP ,FRAP, hsp70,hsCRP, ox- LDL ,leptinand HOMA in patients with type 2diabetes

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effects of vitamin c supplementation, as an antioxidant agent, on advanced glycation end products(AGEs), Advanced Oxidation Protein Products(AOPP) and Ferritin Reducing Ability of Plasma (FRAP) , heat shock protein 70 (hsp70), CRP, ox-LDL(oxidized LDL) , leptin and insulin resistance in patients with type 2 diabetes mellitus.

##### Design

Randomized double blind clinical trial including 70 patients with type2 diabetes.

##### Settings and conduct

This is a randomized double blind clinical trial study on 70 patients with type2 diabetes. After evaluation of inclusion and exclusion criteria, patients will be randomly divided into 2 groups including vitamin C and placebo group. Vitamin C and placebo will prescribe to each group for 2 months. Before treatment and after 2 month blood samples will be taken and stored at -70 c. All samples will be analyzed by standard methods. This study will be conducted at diabetes clinic of the vali-asr hospital which is affiliated with Tehran University of Medical Sciences,Tehran,Iran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria; type2 diabetes, age more than 30 year.  
Exclusion criteria ; type1 diabetes, pregnancy, current vitamins use, renal failure, history of heart failure, smoking, liver failure, malignancy, hypersensitivity to vitamin C, acute inflammation and infection.

##### Intervention groups

In this study intervention is prescription of vitamin c and it's placebo randomly in 2 groups.

##### Main outcome variables

Advanced glycation end products(AGEs), Advanced Oxidation Protein Products(AOPP), Ferritin Reducing Ability of Plasma (FRAP), heat shock protein 70 (hsp70), CRP, ox-LDL(oxidized LDL), leptin and insulin resistance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160811029306N1**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **prospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

##### Registration date

2018-10-06, 1397/07/14

##### 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

2018-10-23, 1397/08/01

##### Expected recruitment end date

2019-01-21, 1397/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effects of ascorbic acid on AGEs, AOPP ,FRAP, hsp70,hsCRP, ox- LDL ,leptinand HOMA in patients with type 2diabetes

## Public title

Vitamin c in Diabetes

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

type2 diabetes older than 30

### Exclusion criteria:

type1 diabetes pregnancy renal failure history ofheart failure liver failure malignancy smoking acute inflammation infection hypersensitivity to vitamin C current vitamins use

## Age

From **30 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Data analyser

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

This is a randomized double blind clinical trial study.

## 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 National Institute for Medical Research Development

##### Street address

No 21, Besat Ave, West Fatemi Blvd,Tehran

##### City

Tehran

##### Province

Tehran

## Postal code

۱۴۱۹۶۹۳۱۱۱

## Approval date

2018-07-01, 1397/04/10

## Ethics committee reference number

IR.NIMAD.REC.1397.123

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

Advancedglycation end products(AGEs)

#### Timepoint

Blood samples will be taken before treatment and after 2 month of treatment.

#### Method of measurement

AGEs will be measured by the spectrophotometric method in endocrine laboratory of vali-asr hospital.

### 2

#### Description

AOPP

#### Timepoint

Blood samples will be taken before treatment and after 2 month of treatment.

#### Method of measurement

AOPP concentrations will be measured by spectrophotometric methods

### 3

#### Description

FRAP

#### Timepoint

Blood samples will be taken before treatment and after 2 month of treatment.

#### Method of measurement

FRAP will be assessed by spectrophotometric method

### 4

#### Description

ox LDL

#### Timepoint

Blood samples will be taken before treatment and after 2 month of treatment.

#### Method of measurement

OX LDL will be measured using commercially available

sandwich enzymelinked immunosorbent assay

## 5

### **Description**

HSP70

### **Timepoint**

Blood samples will be taken before treatment and after 2 month of treatment.

### **Method of measurement**

HSP70 will be measured using a quantitative sandwich ELISA immunoassay

## 6

### **Description**

Hs-CRP

### **Timepoint**

Blood samples will be taken before treatment and after 2 month of treatment.

### **Method of measurement**

Hs-CRP will be assessed by a two-site enzyme-linked immunosorbent assay

## 7

### **Description**

Leptin

### **Timepoint**

Blood samples will be taken before treatment and after 2 month of treatment.

### **Method of measurement**

Leptin leptin concentration will be measured by an ELISA assay

## 8

### **Description**

Insulin

### **Timepoint**

Blood samples will be taken before treatment and after 2 month of treatment.

### **Method of measurement**

Fasting insulin was measured using radioimmunoassay techniques

## **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 Vali-asr Hospital

##### **Full name of responsible person**

Manouchehr Nakhjavani

##### **Street address**

No 20, Keshavarz Blvd, Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

14197-33147

##### **Phone**

+98 21 6691 1294

##### **Email**

nakhjavanim@tums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

National Institute for Medical Research Development

##### **Full name of responsible person**

Reza Malekzadeh

##### **Street address**

No 21, Besat Ave, West Fatemi Blvd, Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

۱۴۱۹۶۹۳۱۱۱

##### **Phone**

+98 21 6690 0920

##### **Email**

NIMAD@RESEARCH.AC.IR

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

National Institute for Medical Research Development

#### **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

**Phone**

+98 21 6691 1294

**Email**

nakhjavanim@tums.ac.ir

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Manouchehr Nakhjavani

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Endocrinology and metabolism

**Street address**

No 21,Vali- asr hospital, Keshavarz Bolvd, Tehran,Iran

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Tehran University of Medical Sciences

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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**

Given the confidentiality of the information of the patients participating in this study, I do not intend to publish the participant's data 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