

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### A clinical trial to compare the effectiveness of vitamin C with placebo on fast blood sugar and hemoglobin A1C levels on type 2 diabetes patient.

#### Protocol summary

##### Study aim

A clinical trial to compare the effectiveness of vitamin C with placebo on fast blood sugar and hemoglobin A1C levels on type 2 diabetes patient

##### Design

54 patients whose type 2 diabetes and visited at diabetes Clinic of Imam Reza Hospital were chosen randomly and assigned to control and intervention groups. A code was allocated to each of the participants.

##### Settings and conduct

Patients with type 2 diabetes visiting at diabetes clinic of Department of Imam Reza Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes who receive only oral diabetes treatment that have not changed their treatment for last three months; Having HbA1c less than 8. Exclusion criteria: Having kidney stones, GFR less than 60, having gestational diabetes, insulin-treated patients; pregnant women.

##### Intervention groups

The intervention group are revising 4 tablets of 250 mg of vitamin C (Producing by Iranian pharmaceutical company) per day for 3 months. The control group are revising 4 tablets of 250 mg of placebo (Having same color of vitamin C tablets without any active ingredient) per day for 3 months.

##### Main outcome variables

Evaluation and comparison of the amount of fast blood sugar (FBS), hemoglobin A1C (HbA1C), Cholesterol, triglyceride (TG), HDL and LDL levels by laboratory experiment in the intervention and control groups before, and 3 months after intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180627040253N1**

Registration date: **2018-07-02, 1397/04/11**

Registration timing: **prospective**

Last update: **2018-07-02, 1397/04/11**

Update count: **0**

##### Registration date

2018-07-02, 1397/04/11

##### Registrant information

###### Name

Behzad Razavi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3854 3031

###### Email address

razavib@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-02, 1397/07/10

##### Expected recruitment end date

2019-10-02, 1398/07/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to compare the effectiveness of vitamin C with placebo on fast blood sugar and hemoglobin A1C levels on type 2 diabetes patient.

##### Public title

The effect of vitamin C on type 2 diabetes patient.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with type 2 diabetes who receive only oral diabetes treatment that have not changed their treatment for last three months Having HbA1c less than 8

### Exclusion criteria:

Having kidney stones, , , GFR less than 60 Having gestational diabetes Insulin-treated patients pregnant women

## Age

No age limit

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: 54

## Randomization (investigator's opinion)

Randomized

## Randomization description

54 patients whose type 2 diabetes and visited at diabetes Clinic of Imam Reza Hospital were chosen randomly based on random numbers table is compiled by computers that regulate the numbers randomly, and assigned to control and intervention groups. A code was allocated to each of the participants.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients with type 2 diabetes and visited at diabetes Clinic of Department of Imam Reza Hospital, are chosen as the participants of the study. In this double-blind study, the participants and responsible for data collection are unaware of type of drug.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for Research, Mashhad University of

Medical Sciences, Ghoreishi building, Daneshgah Street

## City

Mashhad

## Province

Razavi Khorasan

## Postal code

9195965919

## Approval date

2018-04-30, 1397/02/10

## Ethics committee reference number

IR.mums.fm.rec 1397.160

## 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

the amount of fast blood sugar (FBS), hemoglobin A1C (HbA1C), Cholesterol, triglyceride (TG), HDL and LDL levels

#### Timepoint

before, and 3 months after intervention

#### Method of measurement

Laboratory experiment

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: who are revising 4 tablets of 250 mg of placebo (Having same color of vitamin C tablets without any active ingredient) per day for 3 months. Fast blood sugar (FBS), hemoglobin A1C (HbA1C), Cholesterol, triglyceride (TG), HDL and LDL levels will be measured by laboratory experiment before, and 3 months after intervention.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: who are revising 4 tablets of 250 mg of vitamin C (Producing by Iranian pharmaceutical company) per day for 3 months. Fast blood sugar (FBS),

hemoglobin A1C (HbA1C), Cholesterol, triglyceride (TG), HDL and LDL levels will be measured by laboratory experiment before, and 3 months after intervention.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Behzad Razavi

**Street address**

Imam Reza Hospital, Ibn Sina Avenue, Imam Reza Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3802 2000

**Email**

emamreza@mums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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**Province**

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**Postal code**

913750345

**Phone**

+98 51 3841 1538

**Email**

vcresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Behzad Razavi

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Imam Reza Hospital, Ibn Sina Avenue, Imam Reza Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

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**Email**

razavib@mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Behzad Razavi

**Position**

Resident

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Behzad Razavi

**Position**

Resident

**Latest degree**

Specialist

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**Email**

razavib@mums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The total data to be included are the primary and secondary effects to be shared.

**When the data will become available and for how long**

6 months after printing results

**To whom data/document is available**

Our data will only be available to researchers working in science center and university. Under which criteria data/document could be used

**Under which criteria data/document could be used**

Our data will be available for scholars working in science center and university.

**From where data/document is obtainable**

Behzad Razavi provides the analysis code to the applicants via email: razavib@mums.ac.ir

**What processes are involved for a request to access data/document**

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

**Comments**