

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

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9137913316

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+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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913750345

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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

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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

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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