

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effect of Selenium and vitamin C supplementation on Hba1c levels in patients with diabetes type 2

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Effect of selenium supplementation and vitamin C on Hemoglobin A1c in type 2 diabetic patients

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

Update count: **0**

Design

The clinical trial included control group with parallel group, One blind, Randomized by the random numbers of the participants.

Registration date

2018-10-06, 1397/07/14

Settings and conduct

Determine the effect of selenium supplementation and vitamin C on Hemoglobin A1c in type 2 diabetic patients in Bushehr in 2017. Sampling in the laboratory of the Khalij hospital in Bushehr, One blind spot (participants) with Simulation of supplementation and placebo, randomized.

Registrant information

Name

Abbas Yousefinejad

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 3345 0178

Email address

a.yousefinezhad@bpums.ac.ir

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Patients with diabetes type 2, patients with age between 25 to 65 years. Exclusion Criteria: Patients with diabetes type 1, patients with age less than 25 or more than 65, patients with kidney stone.

Recruitment status

Recruitment complete

Funding source

Intervention groups

The effect of selenium supplementation and vitamin C on four random groups include: 1.Recipient Group with selenium and vitamin C 2.Recipient Group with selenium 3.Recipient Group with vitamin C 4.Recipient Group with placebo

Expected recruitment start date

2018-06-27, 1397/04/06

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Determine the Serum levels of Hemoglobin A1c in patients with diabet type 2; Determine the effect of selenium on Hemoglobin A1c in patients with diabet type 2; Determine the effect of vitamin C on Hemoglobin A1c in patients with diabetes type 2.

Scientific title

Effect of Selenium and vitamin C supplementation on Hba1c levels in patients with diabetes type 2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160514027879N3**

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

Public title

Effect of Selenium and vitamin C supplementation on Hba1c levels in patients with diabetes type 2

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

patients with diabetes type 2 and between 25 to 65 years old

Exclusion criteria:

patients with diabetes type 1, pregnancy, patients with kidney stone

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization, individual Randomization, based on the random numbers of participants.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants, Simulation of supplementation and placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences, Moallem St, Kuy-e-Bandar, Bushehr, Iran

City

Bushehr

Province

Bushehr

Postal code

7518759577

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.BPUMS.REC.1396.152

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11.28

ICD-10 code description

Type 2 diabetes mellitus with unspecified complications

Primary outcomes

1

Description

Hemoglobin A1c

Timepoint

7 days before intervention and 3 months after intervention

Method of measurement

Specific Kit for measuring the Hba1c levels

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Selenium Receiving Group

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin C Receiving Group

Category

Treatment - Drugs

3

Description

Intervention group: Selenium and Vitamin C Receiving Group

Category

Treatment - Drugs

4

Description

Control group: Placebo Receiving Group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The Shohadaye Khalije Fars Hospital of Bushehr province

Full name of responsible person

Abbas Yousefinejad

Street address

Shahid Taleghani Boulevard. Bushehr

City

Bushehr

Province

Boushehr

Postal code

7517933755

Phone

+98 77 3345 5375

Email

MPGH@BPUMS.AC.IR

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

Street address

Bushehr university of medical sciences, Salman Farsi Street, Bushehr

City

Bushehr

Province

Boushehr

Postal code

7518759577

Phone

+98 77 3345 0178

Email

Research@bpums.ac.ir

Grant name

80000000 Rial

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

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Abbas Yousefinejad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Moallem St, Bushehr Province, Bandar Bushehr, Kuye-Bandar

City

Bushehr

Province

Boushehr

Postal code

7514633341

Phone

+98 77 3332 2081

Email

a.yousefinezhad@bpums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Abbas Yousefinezhad

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Moallem street, Bushehr

City

Bushehr

Province

Boushehr

Postal code

7514633341

Phone

+98 77 3332 2081

Email

a.yousefinezhad@bpums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Abbas Yousefinezhad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Moallem street, Bushehr

City

Bushehr

Province

Boushehr

Postal code

7514633341

Phone

+98 77 3332 2081

Email

a.yousefinezhad@bpums.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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Information about the changes of principle message

When the data will become available and for how long

beginning of the access period from 2019

To whom data/document is available

for all researches, Professors and students .

Under which criteria data/document could be used

according to the ethical instructions and obey Copy Right

From where data/document is obtainable

Corresponding author

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

Corresponding with the first author

Comments