Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

Investigating the effect of vitamin C supplementation on total salivary antioxidant capacity in patients with type 2 diabetes: A randomized controlled trial

Protocol summary

Study aim

Determining the effect of vitamin C supplementation on total salivary antioxidant capacity in patients with type 2 diabetes

Design

A randomized, controlled, single-blind, parallel-group clinical trial on 80 diabetic patients, who will be allocated into two equal groups using block randomization.

Settings and conduct

This study will be conducted at the specialized diabetes clinic of Valiasr Hospital in Birjand. Unstimulated saliva samples (greater than or equal to 1 mL collected over 5 minutes using a sterile 5 mL Falcon tube) will be taken from participants before and after the four-week intervention, following a 1-hour fast from food, beverages, tobacco, and gum and an initial mouth rinse with sterile saline. Samples will be immediately centrifuged for 15 minutes to remove squamous cells and impurities, then stored at -20°C until analysis for Total Antioxidant Capacity. Blinding:Personnel involved in sample collection and Total Antioxidant Capacity (TAC) laboratory analysis, as well as the statistical analyst, will be blinded to group allocation. The analyst will only access coded group data.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: · Age between 30 and 65 years · Definitive diagnosis of type 2 diabetes by a specialist physician Exclusion Criteria: · Having type 1 diabetes · Consumption of antioxidant supplements (such as vitamins E, C, A, or folic acid) and medicinal or antioxidant mouthwashes over the past month

Intervention groups

Intervention group: Patients with type 2 diabetes who will take one tablet containing 1000 mg of vitamin C (ascorbic acid) daily for 4 consecutive weeks. Control group: Patients with type 2 diabetes who will not receive the vitamin C supplement

Main outcome variables

The total antioxidant capacity of saliva will be measured using the FRAP (Ferric Reducing Antioxidant Power) kit from Kavosh Aryan Azma Company.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251125068106N1**
Registration date: **2025-12-06, 1404/09/15**
Registration timing: **prospective**

Last update: **2025-12-06, 1404/09/15**
Update count: **0**

Registration date

2025-12-06, 1404/09/15

Registrant information

Name

Sajjad Labbafi Esfahrood

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-10, 1404/09/19

Expected recruitment end date

2026-10-11, 1405/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin C supplementation on total salivary antioxidant capacity in patients with type 2 diabetes: A randomized controlled trial

Public title

Investigating the effect of vitamin C supplementation on total salivary antioxidant capacity in patients with type 2 diabetes: A randomized controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 30 and 65 years Definitive diagnosis of Type 2 Diabetes by a specialist physician (based on medical records or treatment history) according to the guidelines: Fasting Blood Sugar (FBS) greater than 126 mg/dL, or HbA1c greater than 6.5%. Stability of the diabetes control medication regimen within the past month Ability to cooperate in saliva sampling Written informed consent to participate in the study

Exclusion criteria:

Diagnosis of type 1 diabetes Use of antioxidant supplements (such as vitamins E, C, A, or folic acid) and medicated or antioxidant mouthwashes within the past month Presence of other chronic systemic diseases requiring long-term medication (such as kidney or liver diseases, or malignancies) Presence of severe diabetes complications (such as advanced retinopathy, neuropathy, or nephropathy) Regular abuse of alcohol or tobacco Presence of salivary gland diseases or conditions impairing salivary secretion, and active clinical symptoms of oral diseases (such as periodontitis, gingivitis, or mucosal lesions) Missed supplement intake more than twice a week Unwillingness to continue participation in the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to the intervention (A) and control (B) groups using block randomization with a block size of 4. The six possible arrangements for blocks containing two A and two B assignments are: 1. AABB, 2. ABAB, 3. ABBA, 4. BBAA, 5. BABA, 6. BAAB. Using the RANDBETWEEN(1,6) function in Excel, 20 blocks will be randomly selected to generate the allocation sequence. Participants will then be assigned to the intervention or control group in a 1:1 ratio according to this sequence. An independent person not involved in data collection will perform the randomization. To ensure allocation concealment, the sequence will be placed in sequentially numbered, sealed, opaque envelopes. These envelopes will be opened only after a participant is enrolled, at which point the participant will be assigned to the corresponding group

Blinding (investigator's opinion)

Single blinded

Blinding description

The individuals responsible for collecting saliva samples and performing the laboratory assay of total antioxidant capacity (TAC) will not be aware of the group assignment. Furthermore, the statistical analyst will only work with the group codes and will not have access to the intervention or control status of the samples.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, Birjand University of Medical Sciences

Street address

Central Administration, Birjand University of Medical Sciences Ghaffari Street Birjand South Khorasan ,Iran

City

Birjand

Province

South Khorasan

Postal code

9717853076

Approval date

2025-11-19, 1404/08/28

Ethics committee reference number

IR.BUMS.REC.1404.361

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
Total antioxidant capacity of saliva
Timepoint
Before the start of the intervention and after the end of the intervention (4 weeks later)
Method of measurement
The total antioxidant capacity of saliva will be measured using the FRAP (Ferric Reducing Antioxidant Power) method from Kavosh Aryan Azma Company. This method is based on the reduction of Fe^{3+} (ferric) ions to Fe^{2+} (ferrous) ions in the presence of the TPTZ (Triypridyl-S-Triazine) reagent, leading to the formation of a blue-colored Fe^{2+}–TPTZ complex with absorbance at a wavelength of 593 nm. The color intensity is measured by a spectrophotometer and represents the antioxidant capacity of the sample.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with type 2 diabetes who will receive one tablet containing 1000 mg of vitamin C (ascorbic acid) daily for 4 consecutive weeks. These tablets are for oral administration, preferably taken at noon with a meal. Supplement brand and manufacturer: Eurovital brand, Hekimane Teb Kär company.
Category
Treatment - Drugs

2

Description
Control group: Patients with type 2 diabetes who will not receive vitamin C supplements.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic, Vali-Asr Hospital, Birjand
Full name of responsible person
Dr. Hossein Dehghani
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Valiasr Educational-Medical Center, Ghaffari Street, Birjand, South Khorasan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person

Sajjad Labbafi Esfahrood

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Position
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Latest degree
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Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available