Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of an artificial saliva produced from aqueous extract of Okra (Abelmoschus Esculentus) on the xerostomia symptoms in diabetic patients

Protocol summary

Study aim

To determine the effect of artificial saliva derived from aqueous extract of okra (Abelmoschus Esculentus) on symptoms of dry mouth in diabetic patients.

Design

A controlled, parallel-group, double-blind, block-based randomized, clinical trial, phase 3, on 80 patients

Settings and conduct

In Birjand Dental School, 80 patients who meet the inclusion criteria will participate in the study with their consent. They will be randomly divided into two groups, complete the Persian version of the Fox questionnaire, receive different combinations, and to investigate the effect of these combinations in different groups after the end of the intervention (day 15 of the study), the Persian version of the Fox questionnaire will be used to determine the effect of the interventions on dry mouth. Blinding: Using identical coded packaging. Blinded individuals: researcher, patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18-65 years; dry mouth based on completion of the Fox questionnaire with a positive answer (yes) to at least 4 questions of the questionnaire; diabetes based on the criteria for diagnosing diabetes. Exclusion criteria: Pregnancy; use of saliva-reducing drugs, using other artificial saliva products; history of autoimmune disorders; pneumonia; presence of oral or perioral lesions; sensitivity to okra, death; development of oral and perioral lesions; decision of the individual or their legal guardian to withdraw from the study.

Intervention groups

(Case group): People in this group included 40 patients, using aqueous extract of okra fruit 3 times a day for two weeks (Positive control group): People in this group included 40 patients, using carboxymethyl cellulose solution 3 times a day for two weeks

Main outcome variables

The score obtained in the Fox questionnaire is measured before the start of the intervention and after the end of the intervention on the 15th day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250311065040N1**
Registration date: **2025-04-22, 1404/02/02**
Registration timing: **prospective**

Last update: **2025-04-22, 1404/02/02**
Update count: **0**

Registration date

2025-04-22, 1404/02/02

Registrant information

Name

Hossein Shirmehenji

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-12-06, 1404/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of an artificial saliva produced from aqueous extract of Okra (Abelmoschus Esculentus) on the xerostomia symptoms in diabetic patients

Public title

Evaluation of the effect of an artificial saliva produced from aqueous extract of Okra (Abelmoschus Esculentus) on the xerostomia symptoms in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Be between the ages of 18 and 65 years old Patients must have dry mouth, based on the Fox questionnaire with at least a positive response to 4 of the 9 questions on the questionnaire Diabetes based on diabetes diagnosis criteria

Exclusion criteria:

Pregnancy Taking medications that reduce salivation Use of other artificial saliva products History of autoimmune diseases History of pneumonia Presence of oral or perioral lesions

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups 1 (intervention) and 2 (control) using a block randomization method, for this purpose, blocks of four are formed including A, B. (For example: AABB, BABA, ABAB) Then, until the sample is completed, the blocks are selected by simple random selection. Also, A will be the intervention group (artificial saliva containing aqueous extract of okra) and B will be the control group (artificial saliva containing carboxymethyl cellulose).

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants and the principal investigator (student performing the intervention and collecting the data) will be blinded by packaging the artificial saliva in the same way and not being aware of the assignment of individuals to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghafari

City

Birjand

Province

South Khorasan

Postal code

91717853076

Approval date

2025-03-15, 1403/12/25

Ethics committee reference number

IR.BUMS.REC.1403.469

Health conditions studied

1

Description of health condition studied

Xerostomia

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

Score obtained on the Fox questionnaire

Timepoint

Days 0 and 14 of the study

Method of measurement

Fox Dry Mouth Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: People in this group, including 40 patients, will rinse their mouths with 2 ml of aqueous extract of okra fruit (30 g sorbitol, 11.7 g aqueous extract of okra, 804 mg dipotassium mono hydrogen phosphate, 625 mg potassium chloride, 366 mg potassium dihydrogen phosphate, 166 mg calcium chloride, 59 mg magnesium chloride, and sodium benzoate at a rate of 0.05% of the total solution as a preservative in 1000 g distilled water) 3 times a day for 2 weeks.

Category
Treatment - Drugs

2

Description
Control group: People in this group, including 40 patients, will rinse their mouths with 2 ml of carboxymethylcellulose solution with the formula (30 g sorbitol, 11.7 g carboxymethylcellulose, 804 mg dipotassium mono hydrogen phosphate, 625 mg potassium chloride, 366 mg potassium dihydrogen phosphate, 166 mg calcium chloride, 59 mg magnesium chloride and sodium benzoate at a rate of 0.05% of the total solution as a preservative in 1000 g distilled water) 3 times a day for 2 weeks.

Category
Treatment - Drugs

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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South Khorasan, Birjand, Ghaffari Street, Vali Asr Educational and Medical Center

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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
Hossein Shirmehenji

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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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
There is no further information.
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