

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A comparative study on the effect of Ginger and Aloe vera mouthwashes on xerostomia among patients with diabetes mellitus

Protocol summary

Study aim

Determination of the effect of Ginger and Aloe vera mouthwashes on xerostomia of patients with diabetes mellitus referred to diabetes clinic of Bandar Abbas in 2019

Design

A clinical trial with a control group, with parallel group design, triple-blind, randomized using the random numbers table. There are three groups: 1- Aloe Vera mouthwash 2- ginger mouthwash and 3- normal saline mouthwash (placebo). The sample size in each group is 35 people. Blinding: All three mouthwashes will be produced by the Barij pharmaceutical company in similar packaging with different A, B and C codes. The researcher, the patients, and the statistical analyst will not know which code corresponds to which mouthwash (triple-blind) and just, a non-beneficiary person out of the project, is aware of the content of the bottles. After completing the statistical analysis, the codes will be decoded by him.

Settings and conduct

In this triple blind clinical trial, among diabetic patients referred to Bandar Abbas Diabetes clinic, 105 people who meet the inclusion criteria, randomly were placed into one of three groups. All three groups use 20 ml of mouthwash three times a day, for 14 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic patients with dry mouth According to tools; The tendency to participate in the study; the ability to use mouthwash. Non-inclusion criteria: Pregnancy; known allergies to ginger or aloe vera; existence of ulcers or oral infections; having high physical activity; using mouthwash or artificial saliva.

Intervention groups

Intervention group 1: Aloe Vera mouthwash. Intervention group 2: ginger mouthwash. control group: normal saline mouthwash (placebo). Patients in each group will use their mouthwash 20ml three times a day, for 14 days.

Main outcome variables

Dry mouth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181209041899N1**

Registration date: **2019-10-24, 1398/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-24, 1398/08/02**

Update count: **0**

Registration date

2019-10-24, 1398/08/02

Registrant information

Name

Forouzande Badooei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 6367

Email address

forouzande21@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of Ginger and Aloe vera mouthwashes on xerostomia among patients with diabetes mellitus

Public title

The effect of Ginger and Aloevera mouthwashes on xerostomia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients with dry mouth according to the tools
The tendency to participate in the study the ability to use mouthwash

Exclusion criteria:

pregnancy known allergies to ginger or aloe vera
existence of ulcers or oral infections having high physical activity use of mouthwash or artificial saliva

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using a random number table that is derived from the Randomization Main software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

All three mouthwashes will be produced by Kashan Barij Essans Pharmaceutical Company in similar packages with different codes A, B or C. The researcher, patients, and statistical analyst will be unaware of which code corresponds to which mouthwash (three blind), and only a non-beneficiary person outside the project is aware of the contents of the bottles and after statistical analysis, the codes will be decoded by him.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Nursing and Midwifery faculty, Southern Resalat, Golshahr

City

Bandar Abbas

Province

Hormozgan

Postal code

7919693116

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

IR.HUMS.REC.1397.299

Health conditions studied

1

Description of health condition studied

dry mouth (xerostomia)

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

Oral dry mouth score based on visual analog scale

Timepoint

Measuring the amount of oral dry mouth before the intervention and 14 days after using mouthwash (after the end of the intervention)

Method of measurement

Standard questionnaire for oral dry mouth and visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The recipient of 50% Aloe Vera mouthwash, prepared by Barij Essance Pharmaceuticals, 20 ml, three times daily for 60 seconds (preferably after meals) Duration of use of mouthwash is 14 days

Category

Treatment - Other

2

Description

Intervention group 2: The recipient of 25% ginger mouthwash, prepared by Barij Essance Pharmaceuticals, 20 ml, three times daily for 60 seconds (preferably after meals) Duration of use of mouthwashes is 14 days

Category

Treatment - Other

3

Description

Control group: The recipient of Normal Saline mouthwash, prepared by Barij Essance Pharmaceuticals, 20 ml, three times daily for 60 seconds (preferably after meals) Duration of use of mouthwashes is 14 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes clinic of Bandar Abbas

Full name of responsible person

Elham Imani

Street address

Shahid Mohammadi Hospital; Gomhoury Eslami Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teymoor Aghamollaei

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Grant name

Thesis

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

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Elham Imani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Forouzande Badooei

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

Only information about the outcome

When the data will become available and for how long

Since 1399

To whom data/document is available

researchers

Under which criteria data/document could be used

Use of the data is permitted with the written permission of the responsible author and with the citation of the source.

From where data/document is obtainable

Dr Elham Imani

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

Access to the data file will be possible by sending a request to the author's email.

Comments