

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 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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Bandar Abbas

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shmh@hums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Teymoor Aghamollaei

**Street address**

Nursing and Midwifery faculty, Southern Resalat, Golshahr

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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

**Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**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

### Contact

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**Other areas of specialty/work**  
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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