

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison between the effect of lemon extract and aloe vera on moisturizing oral cavity in patients with dry mouth in ahvaz dental school

#### Protocol summary

##### Study aim

The aim of this study was to compare between the effect of lemon extract and aloe vera and placebo on moisturizing the oral cavity in patients with dry mouth.

##### Design

Phase 2 crossover clinical trial on 30 patients

##### Settings and conduct

Initially, each patient who came to the dental school with complaints of dry mouth, expressed the degree of dry feeling in his/her mouth based on the VAS index. In this index, the number 10 indicates severe dryness and the number 0 indicates no dry mouth. The VAS number recorded on first day (visit day), third day and fifth day. After that at least one week without medication considered as days off. Then the second and third medicines measured in the same way, respectively. Directions: 3 times a day, 5ml each time, for 40 seconds, swirl in the mouth as a mouthwash and then discard.

##### Participants/Inclusion and exclusion criteria

Entry conditions: Age between 18 to 50 years - Dry mouth feeling  
No entry conditions: Taking anti-cancer medicine - History of radiotherapy / chemotherapy - Pregnancy and breastfeeding - History of allergy

##### Intervention groups

Group 1: Aloe vera extract Group 2: Lemon extract Group 3: placebo

##### Main outcome variables

Dry mouth feeling

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200927048847N2**

Registration date: **2020-12-16, 1399/09/26**

Registration timing: **retrospective**

Last update: **2020-12-16, 1399/09/26**

Update count: **0**

##### Registration date

2020-12-16, 1399/09/26

##### Registrant information

###### Name

Leila Rajaei Behbahani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3338 3230

###### Email address

rajaeebehbahani-l@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2020-03-10, 1398/12/20

##### Actual recruitment start date

2019-09-29, 1398/07/07

##### Actual recruitment end date

2020-10-18, 1399/07/27

##### Trial completion date

2020-11-18, 1399/08/28

##### Scientific title

Comparison between the effect of lemon extract and aloe vera on moisturizing oral cavity in patients with dry mouth in ahvaz dental school

##### Public title

Comparison between the effect of lemon extract and aloe vera on moisturizing oral cavity in patients with dry mouth

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Dry mouth feeling Age between 18 to 50 years

### Exclusion criteria:

Taking anti-cancer medicine History of radiotherapy / chemotherapy Pregnancy and breastfeeding History of allergy

## Age

From **18 years** old to **50 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

## Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **3**

3 medicines separately at regular intervals

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **3**

3 medicines separately at regular intervals

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Containers containing 3 medicines (A, B, C) and 3 questionnaires were placed in a opaque envelope by a reliable person who is outside of the study and delivered to the patient. The results can be analyzed only at the end of the research by a statistical consultant.

## Placebo

Used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahvaz Jundishapour University of Medical Sciences

##### Street address

Ahvaz Jundishapour University of Medical Sciences, Esfand St., Golestan

##### City

Ahvaz

## Province

Khouzestan

## Postal code

6135715775

## Approval date

2019-07-14, 1398/04/23

## Ethics committee reference number

IR.AJUMS.REC.1398.288

## 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

Dry mouth feeling based on VAS index

#### Timepoint

Firs, third and fifth day for each medicine

#### Method of measurement

VAS index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Patients who receive Aloe Vera extract from Barij Essence company - Directions: 3 times a day, 5ml each time, for 40 seconds, swirl in the mouth as a mouthwash and then discard.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Patients who receive Lemon extract from one and one company - Directions: 3 times a day, 5ml each time, for 40 seconds, swirl in the mouth as a mouthwash and then discard.

#### Category

Treatment - Drugs

### 3

#### Description

Control group 3: Patients who receive Hygienic pure water from Shahid Ghazi Pharmaceutical Company -

Directions: 3 times a day, 5ml each time, for 40 seconds, swirl in the mouth as a mouthwash and then discard.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ahvaz dental school

**Full name of responsible person**

Sara Rajaei Behbahani

**Street address**

Ahvaz Jundishapour University of Medical Sciences,  
Esfand St., Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715775

**Phone**

+98 61 3320 5168

**Email**

Sara.rajaei@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehdi Ahmadi Moghadam

**Street address**

Ahvaz Jundishapour University of Medical Sciences,  
Esfand St., Golestan

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715775

**Phone**

+98 61 3336 2414

**Fax**

+98 61 3336 1544

**Email**

research@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Sara Rajaei Behbahani

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

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Esfand St., Golestan

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Ahvaz

**Province**

Khouzestan

**Postal code**

6135715775

**Phone**

+98 61 3320 5168

**Email**

Sara.rajaei@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Leila Rajaei Behbahani

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

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Esfand St., Golestan

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Khouzestan

**Postal code**

6135715775

**Phone**

+98 61 3320 5168

**Email**

rajaeebehbahani-l@ajums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Sara Rajaei Behbahani

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

Ahvaz Jundishapour University of Medical Sciences,  
Esfand St., Golestan

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715775

**Phone**

+98 61 3320 5168

**Email**

Sara.rajaeii@gmail.com

## 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