Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 61 3338 3230

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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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Leila Rajaei Behbahani

Position

Assistant professor

Latest degree

Specialist

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