Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of aloe vera and cinnamon on stimulation and moisture absorption in oral mucosa: A double-blind clinical trial

Protocol summary

Study aim
Identifying the effects of aloe vera and cinnamon on stimulating and moisturizing the oral mucosa

Design
80 people who participated in the study were divided into 4 groups, the 4th group is considered as the control group

Settings and conduct
double-blind clinical trial study in the Faculty of Dentistry of Kerman , which is conducted on people with dry mouth in 4 groups: aloe vera extract, cinnamon extract, 50% solution of aloe vera extract and cinnamon, and negative control. XI questionnaire, visual scale (VAS), OHIP-14 questionnaire are used to evaluate dry mouth. In order to check the amount of saliva secretion before and after the intervention, a spitting test is performed. Both participants and investigators will be blinded to treatment assignment. Block randomization is used to control the effect of confounders. In this way, first, a sequence of random numbers of four is generated, and then, after registering the person, the researcher contacts the statistics expert based in the research center, and the person's group is determined, and the desired spray is given to the person.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients between 18 years old and older with dry mouth Exclusion criteria: pregnancy, allergy to cinnamon or aloe vera, history of radiotherapy and chemotherapy, uncontrolled chronic disease and HIV, hepatitis C or hepatitis B infection.

Intervention groups
Intervention group 1 includes patients with dry mouth, who receive the intervention of aloe vera extract. Intervention group 2 includes patients with dry mouth, who receive cinnamon extract intervention. Intervention group 3 includes patients with dry mouth, who receive the intervention of the combination of cinnamon extract and aloe vera. The control group includes patients with dry mouth, who receive normal saline intervention

Main outcome variables
dry mouth

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240804062631N2**
Registration date: **2024-10-08, 1403/07/17**
Registration timing: **retrospective**

Last update: **2024-10-08, 1403/07/17**
Update count: **0**

Registration date
2024-10-08, 1403/07/17

Registrant information
Name
Sina Kakooei
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-07, 1403/06/17
Expected recruitment end date
2024-10-08, 1403/07/17
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of aloe vera and cinnamon on stimulation and moisture absorption in oral mucosa: A double-blind clinical trial

Public title
evaluation of the effect of aloe vera and cinnamon on moisture absorption in oral mucosa

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients 18 years and older Visiting the Faculty of Dentistry

Exclusion criteria:
Pregnancy Allergy to cinnamon or aloe vera History of radiotherapy and chemotherapy Uncontrolled chronic disease HIV, hepatitis C or hepatitis B infection

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method and description of each method: block randomization Randomization Unit: Individual For randomization, one letter from A, B, C, D is assigned to each group. Then 76 envelopes containing one of the 4 letters A, B, C, D are prepared in the number of 19 for each group and are placed inside a box. When each person enters the study, an envelope is randomly selected and opened. and the person is assigned to that group. The study groups will remain confidential until after the analysis of the study results

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the researcher and volunteers to participate in the study, the sprays are numbered with numbers one to four. Barij essence is added to all groups to equalize the smell and taste

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Jahad Ave

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2024-08-13, 1403/05/23

Ethics committee reference number
IR.KMU.REC.1403.253

Health conditions studied

1

Description of health condition studied
XEROSTOMIA

ICD-10 code
R68.2

ICD-10 code description
Dry mouth, unspecified

Primary outcomes

1

Description
Determining the effect of aloe vera and cinnamon on stimulating and moisturizing the oral mucosa

Timepoint
Oral saliva measurement at the beginning of the study (before the start of the intervention) and 14 days after the start of cinnamon and aloe vera spray.

Method of measurement
Spitting test

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: aloe vera extract spray, Three times a day, 3 puffs of spray each time for two weeks, This spray is prepared by a doctor of pharmacy

who is the pharmaceutical consultant of the present project at the research center for oral and dental diseases

Category

Treatment - Drugs

2

Description

The second intervention group: cinnamon extract spray, Three times a day, 3 puffs of spray each time for two weeks,This spray is prepared by a doctor of pharmacy who is the pharmaceutical consultant of the present project at the research center for oral and dental diseases

Category

Treatment - Drugs

3

Description

The third intervention group: Spray an equal solution of cinnamon and aloe vera, three times a day, Three times a day, 3 puffs of spray each time for two weeks, This spray is prepared by a doctor of pharmacy who is the pharmaceutical consultant of the present project at the research center for oral and dental diseases

Category

Treatment - Drugs

4

Description

Control group: Normal saline spray, Three times a day, 3 puffs of spray each time for two weeks, This spray is prepared by a doctor of pharmacy who is the pharmaceutical consultant of the present project at the research center for oral and dental diseases

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Oral and Dental Diseases Research Center

Full name of responsible person
Shahla Kakoei

Street address
Kousar Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr.Abedin Iranpour

Street address
Jahad Ave

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7619813159

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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

Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Sina Kakooei

Position
Assistant professor

Latest degree
Ph.D.

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

Shahla Kakoei

Position

professor

Latest degree

Specialist

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Participant data file, part of the data such as information related to the main outcome.

When the data will become available and for how long

The access period starts 6 months after the publication of the article

To whom data/document is available

Public access after publication of the article

Under which criteria data/document could be used

Using the data published in the article citing the article

From where data/document is obtainable

Correspondence with the corresponding author Shahla Kakoei 09131408974 skakoei@gmail.com

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

The applicant can correspond with the responsible author through email.

Comments