Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The evaluation of effect of purslane and marshmallow combined extract in the Improvement of symptoms of dry mouth

Protocol summary

Study aim
To investigate the effect of syrup containing marshmallow and purslane extracts on improving symptoms of dry mouth, including oral moisture, mucus stickiness, saliva secretion, and swallowing and speech disorders.

Design
A triple-blind, parallel-group, randomized, phase 3 clinical trial on 60 patients. Randomization will be performed using a simple method and sequential allocation.

Settings and conduct
Zahedan Dental School. Participants will be selected from patients with dry mouth. The syrups are coded in identical bottles and are similar in appearance, taste, smell, and consistency. Symptoms of dry mouth will be assessed and recorded before the start of the intervention and in the second and fourth weeks. Data will be collected using a standardized questionnaire and clinical examinations.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of dry mouth based on a standard questionnaire (positive response to at least three questions). Objective dry mouth index above 30. No tobacco, alcohol, or drug use. Not pregnant or breastfeeding. No history of chemotherapy or radiotherapy in the past six months. No use of corticosteroids or drugs that affect saliva secretion. Inclusion criteria: Unwillingness to participate in the study or failure to complete the informed consent form.

Intervention groups
Intervention group: They receive syrup containing marshmallow and purslane extract. The syrup is prescribed as directed for 4 weeks, three times a day, one spoonful at a time. Control group: They receive syrup with the same appearance, consistency, taste, and smell as the intervention syrup, but without the active ingredient, in the same manner as the intervention group.

Main outcome variables
Moisture of the oral mucosa; amount of saliva secretion; reduction of adhesion of the mucosa to the teeth; improvement of swallowing disorders; improvement of speech disorders.

General information

Reason for update

Acronym
PEMD

IRCT registration information
IRCT registration number: **IRCT20191012045067N11**
Registration date: **2025-01-09, 1403/10/20**
Registration timing: **prospective**

Last update: **2025-01-09, 1403/10/20**
Update count: **0**

Registration date
2025-01-09, 1403/10/20

Registrant information

Name
masoomeh shirzaiy

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-20, 1403/11/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of effect of purslane and marshmallow combined extract in the Improvement of symptoms of dry mouth

Public title
The evaluation of effect of purslane and marshmallow combined extract in the Improvement of symptoms of dry mouth
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
To diagnose dry mouth (xerostomia), patients must exhibit symptoms of dry mouth (based on answering at least 3 positive questions from a standard dry mouth questionnaire). No alcohol, cigarettes, or other tobacco products Not pregnant - breastfeeding No history of chemotherapy or radiotherapy in the past six months Not taking corticosteroids
Exclusion criteria:
Lack of cooperation from patients
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Randomization was performed in a simple way. Individuals were randomly assigned to the intervention and control groups based on the order of presentation. Alternate Allocation was used, with one person assigned to the intervention group and the next to the control group. Randomization unit: Randomization was performed on an individual basis, meaning that each participant was placed individually in one of the two groups. Randomization strata: Stratified randomization was not performed in this study. Randomization tool: Allocation was performed based on sequential presentation and was managed manually. No random number table or statistical software was used for this study. How to construct the random sequence: The random sequence was set up through simple sequential division. The first, third, fifth, etc., patients were assigned to the intervention group, and the second, fourth, sixth, etc., patients were assigned to the control group. Allocation Concealment: To maintain neutrality and conceal allocation, the drug and placebo syrups were prepared in identical bottles with identical coding. The researchers, patients, and statistical analysts were unaware of the contents of the bottles, and the procedure was triple-blind.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The blinding of each group is as follows: 1. Participants: Participants are unaware of whether they are in the intervention group (purslane and marshmallow syrup) or the control group (placebo). The intervention and placebo syrups are designed to be completely similar in appearance (color, consistency, taste, and packaging) so that there is no discernible difference. 2. Clinical caregivers (doctors and nurses): The people responsible for prescribing the syrup and caring for the patients are unaware of the type of syrup (intervention or placebo). The syrups are provided in a coded form and the caregivers only provide the participants with instructions for use. 3. Researchers: The principal investigator and the members of the research team who supervise the implementation of the study and collect the data are unaware of the allocation of patients to the intervention and control groups. The coding of the syrups is done by an independent person or team so that the researchers are not influenced by the process of conducting the study. 4. Outcome assessors: The individuals who assess and record treatment outcomes (such as oral moisture, mucosal adhesion, ease of swallowing, etc.) are unaware of the type of intervention or grouping of participants. The data are recorded in coded form to ensure confidentiality during analysis. 5. Data analysts: The data analysis team, which is responsible for processing the information and extracting the results, has access only to the coded data and is unaware of the group allocation. 6. Data safety and monitoring committee (if any): No such committee was formed in this study. Blinding implementation mechanisms: The syrups were prepared and coded by the Traditional Medicine Laboratory of Shahid Beheshti University of Medical Sciences. The code list is kept only by an independent person outside the research team to provide access to the information in case of emergency. All data and questionnaires are recorded in coded form to maintain blinding until the end of data analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Azadegan street-dental school

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Approval date

2024-11-03, 1403/08/13

Ethics committee reference number

IR.ZAUMS.REC.1403.303

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 mucosal moisture: Checking the presence or absence of saliva in the floor of the mouth and the surface of the mucosa through clinical examination.

Timepoint

Measurement time points - Persian: Measurement of outcome variables is carried out at three time points: before the start of the intervention (beginning of the study). Two weeks after the start of the intervention. Four weeks after the start of the intervention (end of the study).

Method of measurement

Oral mucosal moisture: Through clinical examination, observing the presence or absence of saliva on the floor of the mouth and the surface of the mucosa.

2

Description

Salivary secretion rate: Measuring unstimulated saliva by spitting into a test tube (milliliters per minute).

Timepoint

Measurement time points - Persian: Measurement of outcome variables is carried out at three time points: before the start of the intervention (beginning of the study). Two weeks after the start of the intervention. Four weeks after the start of the intervention (end of the study).

Method of measurement

Salivary secretion rate: Collecting unstimulated saliva by spitting into a test tube for 5 minutes and measuring its volume (milliliters per minute).

3

Description

Mucous adhesion: Checking the adhesion of mucus to the teeth and absalon through clinical examination.

Timepoint

Measurement of outcome variables is carried out at three time points: before the start of the intervention (beginning of the study). Two weeks after the start of the intervention. Four weeks after the start of the intervention (end of the study).

Method of measurement

Mucus adhesion: Using the abseiling method (adhesion or non-adhesion of the abseiling to the oral mucosa) in clinical examination.

4

Description

Swallowing disorder: Checking the ability to swallow dry food (such as plain biscuits) without the need to drink water.

Timepoint

Measurement time points - Persian: Measurement of outcome variables is carried out at three time points: before the start of the intervention (beginning of the study). Two weeks after the start of the intervention. Four weeks after the start of the intervention (end of the study).

Method of measurement

Swallowing disorder: Examining the patient's ability to swallow dry food such as plain biscuits without drinking water at the same time.

5

Description

Speech disorder: Checking the need to drink water to speak and assessing the ease of speaking through a questionnaire and interview.

Timepoint

Measurement time points - Persian: Measurement of outcome variables is carried out at three time points: before the start of the intervention (beginning of the study). Two weeks after the start of the intervention. Four weeks after the start of the intervention (end of the study).

Method of measurement

Speech disorder: Assessing the ease of speech through a standard dry mouth

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Syrup containing marshmallow and purslane extract prepared in the laboratory of the Traditional Medicine Research Center of Shahid Beheshti University of Medical Sciences. This syrup contains concentrated aqueous extract of marshmallow and purslane plants (with a plant to water ratio of 1:20), sugar (25%), preservatives (methylparaben and propylparaben 0.2%), and carboxymethylcellulose thickener (0.25%). Standardization was performed based on total polyphenols. Dosage: Amount: One tablespoon. Frequency of use: Three times a day. Duration of use: 4 weeks. Method of use: The syrup was administered orally and participants reported regular consumption according to the instructions. Control group: Placebo with a formulation similar to the intervention syrup (in terms of appearance, taste, odor, and consistency) but without the active ingredient (herbal extract). Ingredients: Sugar (25%), preservatives (methylparaben and propylparaben 0.2%), thickener carboxymethylcellulose (0.25%), and water. Dosage: One tablespoon. Frequency of use: Three times a day. Duration of use: 4 weeks. Placebo and intervention syrup are coded in similar bottles and are presented in a triple-blind manner.

Category
Treatment - Drugs

2

Description
Control group: Control group: Participants in this group receive placebo. The placebo contains ingredients similar to the intervention syrup in terms of appearance, consistency, taste, and odor, but does not contain the active ingredient (marshmallow and purslane extract). Placebo ingredients: Sugar: 25%. Preservatives: Methylparaben and propylparaben (0.2%). Thickener: Carboxymethylcellulose (0.25%). Water. Dosage: Amount: One tablespoon. Frequency of use: Three times a day. Duration of use: 4 weeks. How to use: The placebo is administered orally and participants consume it regularly according to the instructions. Blinding characteristics: The placebo and intervention syrup are coded in similar bottles and do not differ in appearance or other characteristics. Participants, researchers, and outcome assessors are unaware of the type of intervention.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan dental school
Full name of responsible person
Masoomeh Shirzaiy
Street address
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9817699693
Phone
+98 54 3344 1824
Email
shirzaiy@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Masoomeh Shirzaiy
Street address
Azadegan street-dental school
City
Zahedan
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Sistan-va-Balouchestan
Postal code
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Phone
+98 54 3344 1824
Email
shirzaiy@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Zahedan University of Medical Sciences - Vice President of Research and Technology, Faculty of Dentistry
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
Zahedan University of Medical Sciences
Full name of responsible person
Masoomeh Shirzaiy
Position
Faculty
Latest degree

Specialist
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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Masoomeh Shirzaiy
Position
Faculty
Latest degree
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Other areas of specialty/work
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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
Yes - There is 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
Title and more details about the data/document
identified data for primary and secondary outcomes, may be shared upon reasonable request. Additional documents such as the study protocol, statistical analysis plan, and informed consent forms will also be made available for sharing.
When the data will become available and for how long
The period of access to data and documentation will begin 6 months after the publication of the study results and will continue for 2 years.
To whom data/document is available
The study data and documentation will be available to researchers working in academic and scientific institutions, independent researchers, and individuals working in industry working in fields related to the study subject, subject to a justified request and approval by the research team.
Under which criteria data/document could be used
Type of use: Data and documentation may only be used for research and educational purposes, such as conducting new analyses or secondary studies. Any commercial use of the data is not permitted. Requirements for submitting an application: A written application must include a full explanation of the purpose of using the data. A research plan that indicates how the data will be used. A signed agreement by the applicant to maintain confidentiality of the data and cite the original study if the results are published. Analysis limitations: Data analysis must be within the scope of the research objectives stated in the application. Any use outside the scope of the application requires a new license. Monitoring mechanism: The research team will

have the right to monitor how the data is used. If necessary, the data will be provided in an anonymized and confidential manner.

From where data/document is obtainable

Name of the coordinator: Dr. Masoumeh Shirzaei

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

Submitting a written request: The applicant must submit their request in writing to the study coordinator, explaining the purpose of the research and the proposed design. The request must include the following information: Purpose of using the data. Proposed method for analyzing the data. Ensure compliance with the principles of confidentiality and research ethics. Reviewing the request: The research team will review the request and make a decision. This process may take up to 15 business days. Signing the agreement: If the request is approved, the applicant must sign an agreement that includes the terms of use of the data and the obligation to cite the original study in the research results. Preparing and sending the data: The data will be prepared in an anonymized form, along with relevant documentation, and sent to the applicant via email or a secure platform. This step may take up to 10 business days. Total time: The process from submitting the request to receiving the data usually takes about 3 to 4 business weeks. The applicant can contact the study coordinator via email or phone throughout the process to be informed of the status of their application.

Comments