Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Production and evaluation of the efficacy of a new Iranian artificial saliva in controlling the symptoms of dry mouth in patients with Sjogren's syndrome compared to placebo

Protocol summary

Study aim
Introducing and evaluating the effectiveness of a new Iranian artificial saliva in reducing symptoms of dry mouth in patients with Sjögren's syndrome, with the aim of providing a usable treatment option for patients.

Design
A double-blind, block-randomized clinical trial was conducted on 50 patients. Data were analyzed using descriptive statistics, chi-square test for proportion equality, and Fisher’s exact test when needed.

Settings and conduct
A clinical double-blind, block-randomized trial at Golestan Hospital, Ahvaz, assessed artificial saliva vs. placebo in Sjögren’s patients. Fifty patients received randomized solutions in two treatment phases with a one-week washout and used them as needed. The saliva, made with citric acid, glycerin, sodium bicarbonate, and nystatin, was finalized after pH, rheology, cytotoxicity, and antifungal tests.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: • Age between 18 and 80 years • Diagnosis of primary or secondary Sjögren’s syndrome based on the American College of Rheumatology criteria • Presence of xerostomia (dry mouth) symptoms for at least three months • Signed written informed consent for participation in the study Exclusion Criteria: • Known allergy to any component of the artificial saliva • Presence of severe metabolic disorders that significantly reduce physical ability and interfere with proper use of artificial saliva

Intervention groups
Artificial saliva and Placebo

Main outcome variables
Reduced symptoms of dry mouth; Improved questionnaire scores; Increased duration of oral moisture; Patients' preference for using artificial saliva; No cytotoxicity; Favorable stability and antifungal effect.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250226064856N1**
Registration date: **2025-09-01, 1404/06/10**
Registration timing: **prospective**

Last update: **2025-09-01, 1404/06/10**
Update count: **0**

Registration date
2025-09-01, 1404/06/10

Registrant information

Name
Mohammad Shooryabi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-22, 1404/06/31

Expected recruitment end date
2026-03-19, 1404/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Production and evaluation of the efficacy of a new Iranian artificial saliva in controlling the symptoms of dry mouth in patients with Sjogren's syndrome compared to placebo

Public title
Effect of Artificial Saliva on Controlling Dry Mouth in Patients with Sjogren's Syndrome

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The patient's age must be between 18 and 80 years. The patient must have confirmed primary or secondary Sjögren's syndrome. The diagnosis of Sjögren's syndrome must be based on the criteria of the American College of Rheumatology. The patient must have had xerostomia (dry mouth) for at least three months. The patient must be willing to participate in the study. A written informed consent must be obtained from the patient. The diagnosis must be confirmed by a rheumatology specialist. A complete oral and dental examination must be possible at the first visit. The patient must be able to attend follow-up sessions and cooperate with the research team.

Exclusion criteria:
Family history of medical conditions with dry mouth or other oral disorders that could interfere (e.g., chronic oral infections, head and neck cancer with recent treatment that affected saliva). Presence of a disease or industrial/drug condition that would interfere with artificial saliva or its efficacy assessment (e.g., use of strong anti-salivary medications or salivary stimulants that are incompatible with the purpose of the study). Unwillingness or inability to pursue research or inability to provide informed consent. Participation in other clinical trials that could impact the studies. Known sensitivity or allergy to artificial saliva compounds or its ingredients. Pregnancy or breastfeeding (in some studies) or severe immunodeficiency. The presence of an active oral infection or other health conditions that may affect the results.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization of the study, the block randomization method is used in such a way that 50 patients who meet the inclusion criteria are initially divided into five homogeneous blocks A to E of ten people each, based on age, gender, and duration of disease. Then, from the ten patients in each group, five people are randomly divided into two other subgroups of five people. These are known as Group 1 and Group 2.

Blinding (investigator's opinion)
Double blinded

Blinding description
The bottles containing artificial saliva and placebo are prepared identically in terms of shape, color, and volume, and the number 1 or 2 will be written on the bottle. Only the person responsible for the production and packaging of the solutions will know the meaning of these numbers. When a patient enters the study, a code is assigned to them, in which a letter corresponding to the block they belong to and the number 1 or 2 corresponding to the subgroup within the block is assigned, and the next number 1 or 2 indicates the type of solution they are using, and the last number is from 1 to 5, representing the chronological order in which the individual entered the study. For example, the code E-1-2-5 for a patient means that this patient is the fifth patient who entered the study from Block E and Subgroup 1, and the type of solution assigned to them is Solution 2. This code will be written on each questionnaire and will also be communicated to the patient. The code will also be labeled on the bottle.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan Street – Ahvaz Jundishapur University of Medical Sciences

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ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2025-01-10, 1403/10/21

Ethics committee reference number
IR.AJUMS.REC.1403.527

Health conditions studied

1

Description of health condition studied
Sjogren's syndrome
ICD-10 code
M35.0
ICD-10 code description
Sicca syndrome [Sjogren]

Primary outcomes

1

Description
The severity of dry mouth sensation will be measured based on the patient's self-reported score using a Numerical Rating Scale (NRS) from 0 to 10, both before the intervention and after each two-week treatment period.
Timepoint
Measurement of dry mouth severity at baseline (before intervention), at the end of week 2 of solution use, and at the end of week 5 of the study.
Method of measurement
The severity of dry mouth was measured using the Numerical Rating Scale (NRS) from 0 to 10, as reported by the patient.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group received the synthesized artificial saliva solution (10 ml per dose), used three times a day for two weeks.
Category
Treatment - Drugs

2

Description
Control group: Participants in the control group received a placebo solution with the same appearance and dosage (10 ml per dose), used three times a day for two weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Department of Golestan Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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Position

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Latest degree
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can potentially be shared after deidentification of individuals.
When the data will become available and for how long
The access period will begin 6 months after publication of the results
To whom data/document is available
Data may be requested by researchers affiliated with academic and scientific institutions, as well as individuals working in industry.
Under which criteria data/document could be used
Data will be made available to requesters provided they present a reasonable justification that the information they seek cannot be obtained from the published article.
From where data/document is obtainable
To request the documents, please contact via email at: dsshoriabii@yahoo.com
What processes are involved for a request to access data/document
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