Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of toothpaste formulation containing pilocarpine loaded in nano mesoporous silica on the salivasecretion rate in people with dry mouth compared to pilocarpine.

Protocol summary

Study aim
Production of organic toothpaste containing pilocarpine to improve saliva secretion in people with dry mouth and reduce complications resulting from the use of pilocarpine.

Design
This study is a randomized, double-blind clinical study, and the sample size and related calculations will be performed using SPSS. Volunteers will be randomly divided into three groups, each group consisting of 30 people. The test groups will use toothpaste containing 0.5 and 1% pilocarpine, and the control group will use toothpaste without pilocarpine. Both the examiner and the patient are unaware of the type of toothpaste. Before the study, factors that aggravate xerostomia, such as medications, smoking, beverages, sleep patterns, and stress, will be explained to the patients.

Settings and conduct
The toothpaste formulation will be reviewed under the supervision of a pharmacist and a specialist dentist after obtaining informed consent from the subjects. First, patients who complain of dry mouth will be invited to participate in the study by placing a poster at the entrance of the dental school.

Participants/Inclusion and exclusion criteria
The inclusion criteria were the presence of dry mouth for at least 2 months and the patient's age was at least 20 years. Exclusion criteria were asthma, narrow-angle glaucoma, allergy to toothpaste ingredients, pregnancy, breastfeeding, and treatment with artificial saliva or pilocarpine.

Intervention groups
1. Control group: Placebo 2. Treatment group: Toothpaste containing half percent pilocarpine 3. Treatment group: Toothpaste containing one percent pilocarpine After 1 week of treatment, saliva secretion is measured

Main outcome variables
Drug permeability. Ratio of different ingredients in toothpaste formulations.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250420065395N1**
Registration date: **2025-12-13, 1404/09/22**
Registration timing: **prospective**

Last update: **2025-12-13, 1404/09/22**
Update count: **0**

Registration date
2025-12-13, 1404/09/22

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

Expected recruitment start date
2026-04-21, 1405/02/01
Expected recruitment end date
2026-08-23, 1405/06/01
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of toothpaste formulation containing pilocarpine loaded in nano mesoporous silica on the salivasecretion rate in people with dry mouth compared to pilocarpine.

Public title
organic toothpaste
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
the incidence of mouth dryness is 2 months or more The patient is 20 years old or older.
Exclusion criteria:
the criteria for inattention to the study were :to asthma Narrow-angle glaucoma acute iritis allergy to the ingredients of toothpaste pregnancy breastfeeding people who were able to treat their mouths using artificial saliva People who treat their dry mouth using pilocarpine.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan, Esfand Street
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ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2024-09-29, 1403/07/08
Ethics committee reference number
IR.AJUMS.REC.1403.321

Health conditions studied

1

Description of health condition studied
Dry mouth
ICD-10 code
K11.7
ICD-10 code description
Disturbances of salivary secretion

Primary outcomes

1

Description
Saliva volume
Timepoint
Once every 7 days for 2 to 3 months
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In this group, people will take the non-medicated toothpaste without knowing they are in the placebo group. They will be examined for saliva samples and questionnaires every 7 days for 2 to 3 months.
Category
Placebo

2

Description
Intervention group1: In this group, people will receive toothpaste containing half a percent of the drug and will be examined for saliva samples and questionnaires every 7 days for 2 to 3 months.
Category
Treatment - Drugs

3

Description
Intervention group2: In this group, people will receive

toothpaste containing one a percent of the drug and will be examined for saliva samples and questionnaires every 7 days for 2 to 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

70

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

Seyedeh Nesa Mousavipour

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Food safety and Health

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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
Yes - There is 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
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
Access period starts 12 months after results are published.

To whom data/document is available
The copyright to the information and details must be completely reserved and inaccessible until after the patent is registered.

Under which criteria data/document could be used
No one, except the institution or individual who has obtained the patent and purchased the product, and the individual who owns the idea (Seyedeh Nesa Mousavipour) and the owner of the project (Dr. Eskandar Moghimipour), will have the right to know the results, details, and information of the project.

From where data/document is obtainable
seyedeh nesa mousavipour, 09167239970

What processes are involved for a request to access data/document
After reviewing the request, a response will be received within 3 to 7 business days.

Comments