Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The evaluation of the dose-related effect of pilocarpine mouthwash on symptoms and salivary flow rate in patients with xerostomia

Protocol summary

Study aim

The aim of this study is to evaluate the effect of pilocarpine mouthwash on the symptoms and salivary flow rate of patients with xerostomia and also to determine the minimum effective dose to improve the symptoms of xerostomia

Design

This study will be performed as a clinical trial with a control group with parallel double-blind randomized groups of phase 3 on 60 patients. A random number table in sealed envelopes will be used for randomization. Participants will be given pilocarpine mouthwash with concentrations of 1.5%, 1.0%, 2.0% and placebo in four groups.

Settings and conduct

This research will be performed in the oral medicine department of Tabriz faculty of dentistry. Patients with complaints of dry mouth who meet the necessary conditions will enter the study after obtaining informed consent. Patients and the researcher examining patients will be blind to patient grouping. Before the intervention, the feeling of dry mouth will be determined by the VAS criterion and the volume of unstimulated saliva will be calculated in 5 minutes. At the end of the study, these two variables will be evaluated and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria are presence of dry mouth for 3 months or more, age between 20 and 60 years, and informed consent to participate in the study. Exclusion criteria are acute asthma attack or glaucoma with closed angle or acute iris inflammation, pregnancy or lactation, heart disease and cause of dry mouth radiotherapy of the head and neck

Intervention groups

Patients will be divided into 4 groups The first group: placebo The second group: 1.0% pilocarpine mouthwash The third group: 1.5% pilocarpine mouthwash The fourth group: 2.0% pilocarpine mouthwash

Main outcome variables

Salivary flow rate; Symptoms of xerostomia based on VAS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200108046050N1**
Registration date: **2021-12-01, 1400/09/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-01, 1400/09/10**
Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Katayoun Katebi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3335 6955

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katebik@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The evaluation of the dose-related effect of pilocarpine mouthwash on symptoms and salivary flow rate in patients with xerostomia

Public title
Effect of pilocarpine mouthwash on symptoms and salivary flow rate

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
People who have had dry mouth for 3 months or more People with age between 20 to 60 People who have informed consent to participate in the study
Exclusion criteria:
People with acute asthma attack or narrow-angle glaucoma or acute iris inflammation Women who are pregnant or breastfeeding People who have heart disease People whose dry mouth is caused by radiotherapy to the head and neck

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals will be randomly assigned to one of four study groups with the help of a random number table and will receive the intervention of the allocated group. For allocation concealment, the method of sealed opaque envelopes which are numbered sequentially will be used. In this method, each random sequence is recorded on a card. Finally, the lids of the letter envelopes will be glued and placed inside a box. At the beginning of the registration of participants, according to the order of entry of eligible participants to study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is a double-blind randomized clinical trial in which blindness will be performed for both researchers and participants. In this way, after making the mouthwashes, they will be transferred and labeled in containers with the same shape and packaging, and only the number of mouthwashes and placebo will be recorded on the label (blinding of the participants) and only one of the project partners who knows the contents of the mouthwashes will distribute the mouthwashes among patients. Acquiring saliva samples and examinations will be performed by other research partner who is blind to groups (blinding of researchers)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz faculty of dentistry, Golghasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711

Approval date
2021-10-25, 1400/08/03

Ethics committee reference number
IR.TBZMED.REC.1400.714

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
Salivary flow rate

Timepoint
Before intervention, after 30 minutes and 2 weeks after initiation of pilocarpine mouthwash use

Method of measurement
Measurement of the volume of saliva collected in 5 minutes in a calibrated test tube

2

Description
xerostomia symptoms
Timepoint
Before intervention, after 30 minutes and 2 weeks after initiation of pilocarpine mouthwash use
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Placebo 10 ml normal saline serum, Every 8 hours, 30 drops will be mouth washed for 2 minutes
Category
Placebo

2

Description
Intervention group1: Pilocarpine 1% mouthwash: To prepare a mouthwash with a dilution of 1.0%, 5 ml of 2% pilocarpine eye drops Sina darou will be mixed with 9.5 ml of normal saline until a final volume of 10 ml.
Category
Rehabilitation

3

Description
Intervention group 2: Pilocarpine 1.5% mouthwash: To prepare a mouthwash with a dilution of 1.5%, 7.5 ml of 2% pilocarpine eye drops Sina darou will be mixed with 9.5 ml of normal saline until a final volume of 10 ml.
Category
Rehabilitation

4

Description
Intervention group 3: Pilocarpine 2% mouthwash: To prepare a mouthwash with a dilution of 2%, 10 ml of 2% pilocarpine eye drops Sina darou will be used.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Dentistry faculty
Full name of responsible person
Katayoun Katebi
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Katayoun Katebi
Position
Assistant Professor
Latest degree

Specialist

Other areas of specialty/work
Dentistry

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The main outcomes of the study, including saliva volume and symptoms, before and after the intervention, will be published .

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutes, doctors and dentists

Under which criteria data/document could be used
Use of the data for further research or treatment is permitted.

From where data/document is obtainable
Katayoun Katebi 00984133355965 Department of oral medicine, Tabriz faculty of dentistry katebik@tbzmed.ac.ir

What processes are involved for a request to access data/document
The applicant sends request via email and information and data will be sent to email

Comments