Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the effect of 0/3% Pilocarpine mouthwash on xerostomia in diabetic patients with xerostomia

Protocol summary

Study aim
Evaluation of the effect of 0/3 percent Pilocarpine mouthwash on xerostomia in diabetic patients with xerostomia, presented to Kerman Shahid Bahonar hospital diabetes center in year 1402

Design
Clinical trial with control group, triple blinded, crossover groups, phase 3 on 80 patients. Randomized by simple randomization method by the way of shuffling 80 similar cards 40 marked with code A and 40 with B.

Settings and conduct
Sampling is done by convenience method. Researchers attend the diabetes center and explain the conditions of the project. If the inclusion criteria exists, people will be included after obtaining written informed consent. The sample is divided into intervention and control groups with randomization and desired variables will be checked and recorded. For blinding, 80 medicated and 80 placebo mouthwashes with similar appearance will be coded with arbitrary codes A and B, by a person (employee of the Oral Diseases Department of Kerman Dental School) who doesn't benefit from the study. All patients, clinical caregivers, researchers, outcome assessors and data analysts will be blinded to the codes related to mouthwashes.

Participants/Inclusion and exclusion criteria
The sample consists of 80 over 18-year-old patients referred to Diabetes Center of Kerman Bahonar Hospital. The inclusion criteria are diabetes mellitus (according to the American Diabetes Association), dry mouth (according to the Fox questionnaire), willingness and ability to cooperate correctly. History of uncontrolled asthma, gastric ulcer, autoimmune disease, use of drugs affecting the amount of saliva and dry mouth, HIV, hepatitis B and C infections and unwillingness to cooperate are criteria for not entering.

Intervention groups
Intervention group receives 0.3% pilocarpine mouthwash and control group receives placebo mouthwash.

Main outcome variables
Severity of xerostomia ; volume of unstimulated saliva

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220930056061N1**
Registration date: **2023-07-29, 1402/05/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-29, 1402/05/07**
Update count: **0**

Registration date
2023-07-29, 1402/05/07

Registrant information
Name
Shayan Shakeri
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-26, 1402/05/04
Expected recruitment end date
2023-08-09, 1402/05/18
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of 0/3% Pilocarpine mouthwash on xerostomia in diabetic patients with xerostomia

Public title
Effect of Pilocarpine mouthwash on diabetic patients xerostomia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having diabetes mellitus according to the diagnostic criteria of the American Diabetes Association Suffering from dry mouth according to the diagnosis based on the questionnaire of Fox et al desire and physical and mental ability to cooperate and use mouthwash correctly

Exclusion criteria:
History of uncontrolled asthma History of gastric ulcer Reluctance to cooperate with the study Acute or chronic use of medicine or mouthwash used to relieve dry mouth History of autoimmune disease Head and neck radiation therapy Infection with human immunodeficiency virus(HIV), hepatitis type B and hepatitis type C using of drugs effecting on the amount of saliva during the trial

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by simple randomization method. The desired method is done by punching 80 cards with the same appearance, which contain the necessary information to cooperate in the project along with the code related to the group of participants. According to the design of the study, 40 of the cards are coded as A and the other 40 are coded as B. In order to hide the random allocation, the cards are placed in the same opaque sealed envelopes, and after determining the group of each participant, the opened envelope is removed from the sequence. At the time of registration of eligible study participants and after obtaining informed consent, one of the envelopes is allocated to each person, which determines the participant's group. The sequence of random cards and the sealing of card envelopes are done by the researcher Mr. Mohammad Shayan Shakri, and in order to reduce the possible distortions caused by the knowledge of the researchers about the intervention groups, all researchers are blinded. Due to the cross-over design of the study, the randomization sequence was determined only for the initiation treatment.

Blinding (investigator's opinion)
Triple blinded

Blinding description
At the beginning of the study, 80 pieces of drug mouthwash (pilocarpine) and 80 pieces of placebo mouthwash that were prepared in the same color with the same taste and smell in the same packaging and volume were prepared in two separate groups to one person (from the employees of the oral diseases department of the Kerman Faculty of Dentistry)), which is without profit and knowledge of the conditions and results of the study, is delivered, which are coded by them with arbitrary codes A and B. Allocation of mouthwash to the participants is done by randomization according to the mentioned method and based on the study design. All participating patients, clinical caregivers, researchers, outcome assessors and data analysts will not know the type of mouthwash used by people (medicinal or placebo) and the code related to the type of mouthwash. After the implementation and completion of the study and analysis of the results, the knowledgeable person responsible for coding the mouthwashes reveals the type of mouthwash corresponding to each code.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kerman University of medical science

Street address
Kerman University of medical science research and technology department, Ebn e Sina Ave., Somayeh four-way

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Kerman

Province
Kerman

Postal code
7619813159

Approval date
2023-02-13, 1401/11/24

Ethics committee reference number
IR.KMU.REC.1401.513

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
Unstimulated saliva volume of the sample
Timepoint
before the start of the intervention, and 14 and 35 days after using mouthwash
Method of measurement
Saliva draining method, which is one of the simple and practical methods of measuring the volume of non-irritating saliva in studies, in this method, the person is asked to first wash his mouth with distilled or deionized water to empty it of small debris, then swallow the remaining saliva in their mouth and rest for five minutes, then sit in a quiet environment free of factors that stimulate or limit the secretion of saliva, bend their head down and spit the saliva collected in their mouth for 5 minutes from their lower lip into a 50 ml graduated test container (which has been accurately weighed and sterilized).

2

Description
Intensity of xerostomia based on self-report of people
Timepoint
before the start of the intervention, and 14 and 35 days after using mouthwash
Method of measurement
Patients' self-reported questionnaire

3

Description
Intensity of xerostomia based on Fox questionnaire
Timepoint
before the start of the intervention, and 14 and 35 days after using mouthwash
Method of measurement
Fox et. al questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It is recommended for every person to keep 3 ml of 0/3% Pilocarpine mouthwash for 2 weeks in 3 meals a day (preferably after meals) in their mouth for 1 minute each time and then throw it away.
Category
Treatment - Drugs

2

Description
Control group: For 2 weeks, it is recommended for each person to use a placebo mouthwash consisting of the mouthwash excipients under study, which is prepared by essential oil in the same color with the same taste and smell in the same packaging and volume, in 3 meals a day (preferably after meals)) and keep 3 ml in your mouth for 1 minute each time and then throw it away.
Category
Placebo

3

Description
Control group: consists of the (remaining) people of the primary intervention group. due to the crossover design of the study, after the end of the washout period, it is recommended from each person of this group to take placebo mouthwash consisting of the excipients of the studied mouthwash which is prepared in same color, smell, essence in the same packaging and volume, for 2 weeks 3 meals a day (preferably after meals) and keep 3 ml in mouth for 1 minute each time and then throw it away.
Category
Placebo

4

Description
Intervention group: consists of the (remaining) people of the primary control group. due to the crossover design of the study, after the end of the washout period, it is recommended from each person of this group to take Pilocarpine mouthwash for 2 weeks in 3 meals a day (preferably after meals) in their mouth for 1 minute each time and then throw it away.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar Hospital Diabetes Center, Kerman city
Full name of responsible person
Dr.Soosan Hajipoor
Street address

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Email
bahonarhospitalresearch@gmail.com
Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Kerman University of Medical science, Haft bagh alavi blvd., Kerman, Iran
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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

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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

Undecided - It is not yet known if there will be 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