

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the 1% and 2% Pilocarpine mouthwash on xerostomic patients

Protocol summary

Study aim

Comparison of the 1% and 2% Pilocarpine mouthwash on xerostomic patient

Design

48 patients were divided in 3 groups, every group were 16 patients. Double-blind design was performed

Settings and conduct

Islamic Azad University / Dental School

Participants/Inclusion and exclusion criteria

Xerostomic patient was included in research. Exclusion criteria were: milking/pregnancy, mucosal disease, connective tissue disorders, Hepatitis B/C, HIV, Allergy to pilocarpine, hypertension, Herbal drugs, systemic disorders, alcoholism, denture wearing

Intervention groups

G1: 1% Pilocarpine mouthwash
G2: 2% Pilocarpine mouthwash
G3: 0% Pilocarpine mouthwash/placebo

Main outcome variables

Reduce of xerostomia/decrease of dry mouth complications

General information

Reason for update

Correcting the writing, adding some data

Acronym

IRCT registration information

IRCT registration number: **IRCT20210208050302N1**

Registration date: **2021-03-03, 1399/12/13**

Registration timing: **prospective**

Last update: **2022-05-18, 1401/02/28**

Update count: **1**

Registration date

2021-03-03, 1399/12/13

Registrant information

Name

babak motamed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2232 6172

Email address

alae.a@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

2021-04-21, 1400/02/01

Actual recruitment end date

2021-10-22, 1400/07/30

Trial completion date

2021-11-06, 1400/08/15

Scientific title

Comparison of the 1% and 2% Pilocarpine mouthwash on xerostomic patients

Public title

Comparison of the 1% and 2% Pilocarpine mouthwash on xerostomic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

xerostomia

Exclusion criteria:

using chemical/herbal drugs pregnant/milking connective tissue disorders allergy to pilocarpine

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

method : simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient and researcher

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic azad university Tehran medical branch

Street address

No 1 , Golnar Ave., Pasdaran St.

City

Tehran

Province

Tehran

Postal code

1945643174

Approval date

2021-02-15, 1399/11/27

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.282

Health conditions studied

1

Description of health condition studied

Xerostomia, oral medicine, dry mouth, saliva

ICD-10 code

ICD-10-CM

ICD-10 code description

ICD-10-CM Diagnosis Code R85.9

Primary outcomes

1

Description

Saliva rate

Timepoint

in minute 45 & 60 & 75 in first and 14 days after intervention

Method of measurement

Absorbent method

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

islamic azad university/Dental school

Full name of responsible person

dr Babak Motamed

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No.1, Golnar Ave., Pasdaran st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

dr Arezoo Alaei

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+98 21 2251 5700

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arezoo.alaaee@yahoo.com

Grant name
-

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Babak Motamed

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
dr Babak Motamed

Position
Resident of oral medicine

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person
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Position

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Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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oral medicine specialist

Latest degree
Specialist

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Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I need consultation

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
Not applicable

Data Dictionary
Not applicable