Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 were16 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 exclusions criteria were: milking/pregnancy,mucosal disease,connectine tissue disorders,Hepatitis B/C,HIV,Allergy to pilocarpine,hypertension,Herbal drugs,systemic disorders,alcoholism,denture wearing
Intervention groups
G1: 1% Pilocarpin mouthwash G2: 2% Pilocarpin mouthwash G3: 0% Pilocarpin mouthwash/placebo
Main outcome variables
Reduce of xerostomia/decrease of dry mouth complications

General information

Reason for update
correcting the writing,adding some datas
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)
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+98 21 2232 6172
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alaee.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 plocarpine
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 mediacal 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
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Full name of responsible person
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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
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Person responsible for updating data

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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