Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The comparison of therapeutic effect of chewing gum and salivary glands massage, in treatment of xerostomia

Protocol summary

Summary

The purpose of this study is comparison of chewing gum and salivary glands massage in treatment of xerostomia. This study is a randomized clinical trial without placebo. The inclusion criteria is having xerostomia and the exclusion criteria is having mouth drying habits.This study will be done on 60 patients with xerostomia who are referred to Yazd Dentistry School. Intervention for this study, evaluates effect of two different methods including chewing six pieces of sugar free gum with mint flavor per day and salivary glands massage ten times in a day and each time ten times for a period of 3 months. Primary outcome measure includes unstimulated and stimulated whole salivary flow rate which is measured by ml/min.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211149103N2**
Registration date: **2012-12-31, 1391/10/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-31, 1391/10/11

Registrant information

Name

Neda Gholami

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Science, Dental school

Country

Iran (Islamic Republic of)

Phone

+98 35 1622 0022

Email address

drahadian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-04-18, 1391/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of therapeutic effect of chewing gum and salivary glands massage, in treatment of xerostomia

Public title

effect of salivary glands massage in treatment of xerostomia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with xerostomia Exclusion criteria : Drying habits such as mouth breathing

Age

From **18 years** old to **149 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Yazd Shahid Sadoughi University of Medical Sciences
Street address
Central part of the Shahid Sadoughi University of Medical Sciences, Shahid Bahounar Square, Yazd, Iran
City
Yazd
Postal code
8916978477
Approval date
2012-02-27, 1390/12/08
Ethics committee reference number
17/1/153924/پ

Health conditions studied

1

Description of health condition studied
xerostomia
ICD-10 code
k11.7
ICD-10 code description
disturbances of salivary secretion

Primary outcomes

1

Description
unstimulated whole saliva flow rate
Timepoint
before intervention, 3 mounth after starting intervention
Method of measurement
Ml per minute

2

Description
stimulated whole saliva flow rate
Timepoint
before intervention, 3 mounth after starting intervention
Method of measurement
Ml per minute

Secondary outcomes

empty

Intervention groups

1

Description
Sugar free gum with mint flavor/Six pieces per day/3 months
Category
Treatment - Other

2

Description
Salivary glands massage/ ten times per hour, ten hours a day/3 months
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Shadid Sadoughi University of Medical Sciences, Dental School
Full name of responsible person
Narges Mirjalili
Street address
Shahid Sadoughi University of Medical Sciences, Dental School, Fazaye sabz Crossroad, Dahe-fajr Blv, Yazd, Iran
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences, Dental School
Full name of responsible person
Fatemeh Ezodini
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City
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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
Yazd Shahid Sadoughi University of Medical Sciences, Dental School
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences, Dental School
Full name of responsible person
Mehdi Gazerani
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty