

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Bahonar 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 month after starting intervention

#### Method of measurement

MI per minute

### 2

#### Description

stimulated whole saliva flow rate

#### Timepoint

before intervention, 3 month after starting intervention

#### Method of measurement

MI 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

##### Street address

Yazd Shahid Sadoughi University of Medical Sciences, Dental School, Fazaye sabz Crossroad, Dahe-fajr Blv, Yazd, Iran

##### City

Yazd

#### 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

**Position**

under graduate student

**Other areas of specialty/work****Street address**

Yazd Shahid Sadoughi University of Medical Sciences,  
Dental School, Fazaye sabz Crossroad, Dahe-fajr Blv,  
Yazd, Iran

**City**

Yazd

**Postal code****Phone**

+98 35 1621 2222

**Fax****Email**

dent.mehdi@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Narges Mirjalili

**Position**

Specialist in Oral and Maxillofacial Medicine

**Other areas of specialty/work****Street address**

Yazd Shahid Sadoughi University of Medical Sciences,  
Dental School, Fazaye sabz Crossroad, Dahe-fajr Blv,  
Yazd, Iran

**City**

Yazd

**Postal code****Phone**

+98 35 1621 2222

**Fax****Email**

n\_mirjalili@ssu.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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Yazd, Iran

**City**

Yazd

**Postal code****Phone****Fax****Email****Web page address****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*