

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The comparison between the effects of two saliva stimulus and ordinary chewing gums on xerostomia in haemodialysis patients.

Protocol summary

Summary

One of the most important side effects of frequent haemodialysis is xerostomia. So this study tries to compare saliva secretion caused by a specific saliva stimulus chewing gum (Bioten) with an ordinary sugar free one (Orbit) on haemodialysis patients. This study is a clinical, double-blind and cross-over study. In which 30 volunteer haemodialysis patients of two dialysis canter in Isfahan will be randomly classified into two groups. In the first period for 14 days, each group will be given one brand of chewing gum (Bioten or Orbit), to chew 3 gums a day, each time for at least 10 minutes, while the other group will be given the other brand. After a one-week-washout period in between, the second 14 days period will accomplish by changing the brands of chewing gums given to each group. To double blind the study, the gum boxes will be simulated and coded by another person. Before the beginning of the study and after each period, the secreted saliva will be measured. The findings will be statistically analyzed using Pair T, ANOVA and Mann Whitney tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903244174N1**

Registration date: **2010-09-30, 1389/07/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-30, 1389/07/08

Registrant information

Name

Maryam Karami

Name of organization / entity

Islamic Azad University-Khorasgan Branch

Country

Iran (Islamic Republic of)

Phone

+98 31 1778 0149

Email address

mkarami@dental.khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2008-04-20, 1387/02/01

Expected recruitment end date

2008-06-21, 1387/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between the effects of two saliva stimulus and ordinary chewing gums on xerostomia in haemodialysis patients.

Public title

The effect of chewing gum on xerostomia in haemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1-haemodialysis patients 2-informrd consent and willing to cooperate 3-not to chew any other gums during the study Exclusion criteria: unwilling to continue

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Islamic Azad University Khorasgan Branch

Street address

Arghavanieh

City

Esfahan

Postal code**Approval date**

2008-01-03, 1386/10/13

Ethics committee reference number

23810201862005

Health conditions studied**1****Description of health condition studied**

xerostomia in haemodialysis patients

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion; Xerostomia

Primary outcomes**1****Description**

stimulated salivary secretion

Timepoint

14 days

Method of measurement

secreted saliva(measuring the weight of secreted saliva

Secondary outcomes

empty

Intervention groups**1****Description**

chewing Orbit gums in the first period and Biotene gums in the second period

Category

Prevention

2**Description**

chewing Biotene gums in the first period and Orbit gums in the second period

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra and Khorshid dialysis centers

Full name of responsible person

Dr Maryam Karami

Street address

Islamic Azad University Khorasgan Branch

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Investigator

Full name of responsible person

Dr Shakiba Hoseinzade

Street address

Arghavanieh

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Investigator

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

Isfahan

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

Islamic Azad University Khorasgan Branch

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Position

Assistant professor

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City

Esfahan

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