

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of chlorhexidine 0.2% and combination of xylitol and fluoride 920 ppm mouthwashes on salivary Streptococcus mutans count (in vivo)

Protocol summary

Summary

The aim of this study is to evaluate the Anti-caries effect of two common mouthwashes in the market. In this experimental study, 30 Dental students will be selected. Voluntaries will be divided into two groups containing 15 peoples. Saliva samples will be taken from each group. Each group will use the mouthwash for 2 weeks, twice a day, 15 cc for each time, and they will have consume mouthrinses for 30 seconds. Inclusion criteria: not to use antibiotics within past 3 months; DMFT:5-7; not to use xylitol gum; not to use topical fluoride treatments in the last 4 weeks; not to wear orthodontic appliances. Exclusion criteria: not to use the mouthwashes(according to researcher prescription)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016073129133N1**

Registration date: **2016-09-05, 1395/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-05, 1395/06/15

Registrant information

Name

Neda Gholami

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of chlorhexidine 0.2% and combination of xylitol and fluoride 920 ppm mouthwashes on salivary Streptococcus mutans count (in vivo)

Public title

The comparison of chlorhexidine and fuchs Mouthwashes on salivary Cariogenic bacterias in dental students of Zanjan university of medical sciences

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: not to use antibiotics within past 3 months; DMFT:5-7; not to use xylitol gum; not to use topical fluoride treatments in the last 4 weekes; not to wear orthodontic appliances. Exclusion criteria: not to use the mouthwashes(according to researcher prescription)

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

Parallel

Other design features

in this study block randomization was used to randomize the groups

Secondary Ids

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Azadi Square, Zanjan, Zanjan University of Medical Sciences

City

Zanjan

Postal code

13191-45156

Approval date

2016-03-03, 1394/12/13

Ethics committee reference number

zums.rec.1394.291

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

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

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

The amount of Streptococcus mutans in saliva

Timepoint

2 weeks

Method of measurement

Counting colonies in the laboratory

Secondary outcomes**1****Description**

-

Timepoint

-

Method of measurement

-

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

Intervention group:using Fuchs mouthwashe produced by Fuchs(Germany),containing Xylitol and Fluride 920ppm for 2 weeks,twice a day;30 seconds each time

Category

Treatment - Drugs

2**Description**

Control group: using Chlorhexidine 0.2% produced by Najo(Iran) for 2 weeks,twice a day;30 seconds each time

Category

Treatment - Drugs

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

Faculty of dentistry, Zanjan University of Medical Sciences

Full name of responsible person

Dr Elham Zajkani

Street address

Azadi Square, Zanjan, Zanjan University of Medical Sciences

City

Zanjan

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

Vice Chancellor for research of Zanjan University of

Medical Sciences
Full name of responsible person
 dr Masud Vakili
Street address
 Azadi Square, Zanjan, Zanjan University of Medical Sciences
City
 Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice Chancellor for research of Zanjan University of Medical Sciences
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
 Zanjan University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact

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