Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison of chlorhexidine 0.2% and combination of xylitol and fluoride 920 ppm mouthwashs 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 weekes; 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)
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+98 21 7770 1401
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dr.gholami.n@zums.ac.ir

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 mouthwashs on salivary Streptococcus mutans count (in vivo)

Public title

The comparison of chlorhexidine and fichs Mouthwashs 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

Dr Elham Zajkani

Position

Assistant Professor , School of Dentistry Department of restorative Dentistry

Other areas of specialty/work

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Assistant Professor of restorative dentistry

Other areas of specialty/work

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Web page address

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