

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparison of calcium and calcium placebo pre-rinse effect on salivary and plaque fluoride and calcium concentrations after the use of 900 ppm sodium fluoride mouthwash

Protocol summary

Summary

The purpose of this study was to evaluate fluoride and calcium concentrations in saliva and dental plaque after the use of calcium pre-rinse and 900 ppm fluoride mouthwash. Inclusion criteria was good oral hygiene; having at least 24 natural teeth; normal unstimulated whole saliva flow rate; good oral and general health, no dentures and orthodontic appliances and no medications for at least 4 weeks before the project started. In this double-blind, double-crossover clinical trial, 30 dental students will participate. After prophylaxis and oral hygiene practices for 14 days by using non-fluoride products, the first baseline salivary and plaque sampling will be done. Immediately after that, based on a random number sequence, 15 subjects will use 10 ml placebo rinse/10 ml sodium fluoride and the remaining will use 10 ml calcium rinse /10 ml sodium fluoride. One and 12 hours later, samples will be again collected. The subjects then will receive another prophylaxis. Also, they will entirely adhere to previous 2 weeks pre-rinsing instructions. The second baseline samples will then gathered. Afterward, the participants will rinse treatment not previously used. The volume, time, order and duration of rinsing and salivary and plaque sampling (1 and 12 hours samples) will be as the same as explained before. The fluoride and calcium concentration in prepared specimens will be analyzed using an inverted fluoride selective electrode apparatus and atomic absorption spectrophotometry respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404286105N3**

Registration date: **2014-06-01, 1393/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-01, 1393/03/11

Registrant information

Name

Nahid Ramazani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 1341 6706

Email address

ramazani77@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of calcium and calcium placebo pre-rinse effect on salivary and plaque fluoride and calcium concentrations after the use of 900 ppm sodium fluoride mouthwash

Public title

Comparison of calcium and calcium placebo pre-rinse

effect on salivary and plaque fluoride and calcium concentrations after the use of 900 ppm sodium fluoride mouthwash

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Good oral hygiene which was checked clinically by the absence of food debris and plaque accumulations; having at least 24 natural teeth; normal unstimulated whole saliva flow rate (0.25-0.35 ml/min); good oral (no demineralized enamel, no congenital enamel anomaly, no untreated decay, no faulty dental restorations) and general health Exclusion criteria: Dentures and orthodontic appliances; Medications for at least 4 weeks before the project started.

Age

From **18 years** old to **24 years** old

Gender

Male

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

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Daneshgah Street, Zahedan

City

Zahedan

Postal code

Approval date

2011-02-23, 1389/12/04

Ethics committee reference number

6318

Health conditions studied

1

Description of health condition studied

Dental Caries

ICD-10 code

B99-B99

ICD-10 code description

Other infectious diseases

Primary outcomes

1

Description

salivary calcium concentration

Timepoint

1 and 12 hours after intervention 1 and 2

Method of measurement

by spectrophotometry

2

Description

salivary fluoride concentration

Timepoint

1 and 12 hours after intervention 1 and 2

Method of measurement

using fluoride selective electrode

3

Description

dental plaque fluoride concentration

Timepoint

1 and 12 hours after intervention 1 and 2

Method of measurement

using fluoride selective electrode

4

Description

dental plaque calcium concentration

Timepoint

1 and 12 hours after intervention 1 and 2

Method of measurement

by spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: 160 mmol/l calcium lactate mouthwash (Merk, Germany), 10 ml of mouth wash will be rinsed for 1 minutes. Immediately after that, 0.2% NaF mouthwash (Behsa, Iran), 10 ml of mouth wash will be rinsed for 1 minute.

Category

Prevention

2

Description

Intervention 2: Distilled water mouthwash (Iran,), 10 ml of mouth wash will be rinsed for 1 minutes. Immediately after that, 0.2% NaF mouthwash (Behsa, Iran), 10 ml of mouth wash will be rinsed for 1 minute.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences

Full name of responsible person

Nahid Ramazani

Street address

Dental School, Azadegan Avenue, Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nahid Ramazani

Street address

Zahedan University of Medical Sciences, Daneshgah Street, Zahedan

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Nahid Ramazani

Position

Aisstant Professor

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