Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of fluoride mouth rinse and calcium and fluoride mouth rinses on salivary fluoride concentration in dental students

Protocol summary

Summary

During topical fluoride application, fluoride ion can deposit CaF2 material on tooth surface. CaF2 forms a fluoride-releasing and PH-controlling system. Availability of calcium is an important factor for formation of this composition. Unfortunately during application of topical fluoridated products, formation of CaF2 deposits is limited due to low concentration of unbounded oral calcium in relation to applied amount of fluoride. The aim of this study is to evaluate the effect of calcium pre rinse on salivary fluoride concentration after a 900 PPM fluoride mouthwash. In this single blind randomized clinical trial, 42 female dental students with optimal oral hygiene, normal oral mucosal tissue and physiology, at least 20 teeth and suitable restorations and having no enamel defects, systemic diseases and active caries without wearing orthodontic appliances and prostheses, no using drugs affect quality and quantity of saliva and no using of antibiotics or antibacterial mouth rinses during 2 weeks ago will be randomly chosen and use sodium fluoride mouth rinse and after 2 weeks, calcium lactate and then immediately sodium fluoride rinses. Before each experiment, prophylaxis will be done and during the next 2 weeks, the participants will be asked no fluoridated products usage and then rinse with mouthwashes. Salivary samples will be taken immediately before, 1 and 12 hours after rinsing. Samples with coded numbers will be preserved in -20˚C and after collection of all, they will be transported to laboratory to preparation and analysis of fluoride ion, so that type of mouth wash and time of sampling will not be revealed in the laboratory. Determining salivary fluoride concentration will be done via fluoride sensitive electrode.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107306105N2**
Registration date: **2011-09-17, 1390/06/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-09-17, 1390/06/26

Registrant information

Name

Nahid Ramazani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

ramazani77@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Sciences Vice chancellor for research, Zahedan University of Medical

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of fluoride mouth rinse and calcium and fluoride mouth rinses on salivary fluoride concentration in dental students

Public title
Use of calcium pre-rinse before fluoride mouth rinse
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: optimal oral hygiene; having normal oral mucosal tissue and physiology; having at least 20 teeth and suitable restorations Exclusion criteria: having enamel defects or systemic diseases; wearing orthodontic appliances or prostheses; active caries; using drugs affect quality and quantity of saliva; use of antibiotics or antibacterial mouth rinses during 2 weeks ago
Age
From **18 years** old to **24 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Science
Street address
Pardis of Zahedan University of Medical Science, Khalij fars Avenue, Dr Hesabi Square,
City
Zahedan
Postal code
9816743463
Approval date
2011-02-15, 1389/11/26
Ethics committee reference number
3554-89

Health conditions studied

1

Description of health condition studied
the amount of salivary fluoride
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
salivary fluoride
Timepoint
immediately before, 1 and 12 hours after rinsing
Method of measurement
fluoride sensitive electrode

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: 0.2% NaF mouthwash (Behsa, Iran), 10 ml of mouth wash will be rinsed for 1 minutes.
Category
Prevention

2

Description
Intervention 2: 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 minutes.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Department of Zahedan Dental School
Full name of responsible person
Dr. Nahid Ramazani
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School of Dentistry
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2

Recruitment center
Name of recruitment center
Mojtama Khabgah

Full name of responsible person
Dr. Nahid Ramazani
Street address
Mojtama Khabgah- Dr Hesabi Square
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3

Recruitment center
Name of recruitment center
Noor Khabgah
Full name of responsible person
Dr. Nahid Ramazani
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Noor Khabgah- Mashahir Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sciences Vice chancellor for research, Zahedan University of Medical
Full name of responsible person
Dr Mahmud Zade Sagheb
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Pardis of Zahedan University of Medical Science, Khalij Fars Avenue, Dr Hesabi Squre
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sciences Vice chancellor for research, Zahedan University of Medical
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
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Dr Nahid Ramazani
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Assistant professor of pediatric 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