

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 CaF<sub>2</sub> material on tooth surface. CaF<sub>2</sub> 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 CaF<sub>2</sub> 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

+98 54 1341 6706

###### 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

##### Street address

School of Dentistry

##### City

Zahedan

### 2

#### Recruitment center

##### Name of recruitment center

Mojtama Khabgah

**Full name of responsible person**

Dr. Nahid Ramazani

**Street address**

Mojtama Khabgah- Dr Hesabi Square

**City**

Zahedan

**3****Recruitment center****Name of recruitment center**

Noor Khabgah

**Full name of responsible person**

Dr. Nahid Ramazani

**Street address**

Noor Khabgah- Mashahir Square

**City**

Zahedan

**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

**Street address**

Pardis of Zahedan University of Medical Science, Khalij Fars Avenue, Dr Hesabi Squire

**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

**Full name of responsible person**

Dr Nahid Ramazani

**Position**

Assistant professor of pediatric dentistry

**Other areas of specialty/work****Street address**

Dental School, Mehr Avenue

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

Zahedan University of Medical Sciences

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Dr. Nahid Ramazani

**Position**

Pedodontist

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School of dentistry, Mehr Avenue

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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*