

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Effect of nano hydroxyapatite toothpastes and mouth rinse on eroded enamel and dentin - an in situ study

#### Protocol summary

##### Study aim

This study aims to investigate the effect of different toothpaste and mouthwashes on dentin erosion/abrasion (in situ study design) using surface microhardness, roughness and surface wear methods.

##### Design

Randomized clinical trial, with a control group, cross-over, double-blind, phase 3 on 21 patients

##### Settings and conduct

The participants will be selected in Shiraz Dental School. A full explanation about the purpose of the study and how to implement it and its steps will be provided to the participants. The study is double-blind. The patient, the researcher and the interpreter do not know about the grouping.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: being at least 18 years old, having good general and oral health, not being allergic to certain substances including oral hygiene products or dental materials, non-stimulated and stimulated saliva flow more than 0.25 ml/min and more than 0.25 ml/min, respectively. The absence of active caries lesions or non-carious lesions such as cervical lesions and periodontal disease, the absence of dental prostheses and orthodontic appliances, the absence of erosive lesions in the teeth, and the possibility of visiting at recalls.

##### Intervention groups

Group 1 (negative control): distilled water is used in this group (appliance without using toothpaste). Group 2 (positive control): using Elmex ® erosion protection toothpaste followed by Elmex ® erosion protection mouthwash Group 3: using Vitis® anticaries with nanorepair toothpaste . Then use Vitis® anticaries mouthwash

##### Main outcome variables

Surface microhardness, Surface roughness, Surface wear

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110823007402N9**

Registration date: **2023-01-23, 1401/11/03**

Registration timing: **prospective**

Last update: **2023-01-23, 1401/11/03**

Update count: **0**

##### Registration date

2023-01-23, 1401/11/03

##### Registrant information

##### Name

Mahtab Memarpour

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1626 3192

##### Email address

memarpour@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-05, 1402/01/16

##### Expected recruitment end date

2023-05-06, 1402/02/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of nano hydroxyapatite toothpastes and mouth rinse on eroded enamel and dentin - an in situ study

**Public title**

Effect of nano hydroxyapatite toothpaste and mouthwash on enamel and dentin erosion

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

1) Being at least 18 years old 2) Having good general and oral health 3) Not being allergic to certain substances including oral hygiene products or dental materials 4) Non-stimulated and stimulated saliva flow more than 0.25 ml/min and more than 0.25 ml/min, respectively. 5) The absence of active caries lesions or non-carious lesions such as cervical lesions and periodontal disease 6) The absence of dental prostheses and orthodontic appliances 7) The absence of erosive lesions in the teeth 8) The possibility of visiting at recalls.

**Exclusion criteria:**

1) Pregnancy or intention to become pregnant during the study 2) Breastfeeding 3) Simultaneous participation in another study 4) Professional use of fluoride in the last two months 5) Inability to implement the study protocols 6) Receiving medical treatment 7) Using drugs that Interference with the flow of saliva 8) Having digestive problems 9) Smoking

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **21**

More than 1 sample in each individual

Number of samples in each individual: **8**

-

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization, block. The size of all the blocks will be equal. Sequence generation software is also used for randomization. Sequentially numbered, sealed, opaque envelopes are used for random concealment. In this method, each random sequence created is recorded on a card and the cards inside and the letter envelopes are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The size of all the blocks will be equal. Sequence generation software is also used for randomization. Sequentially numbered, sealed, opaque envelopes are used for random concealment. In this method, each random sequence created is recorded on a card and the cards inside and the letter envelopes are placed in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Administration Building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Approval date**

2022-10-19, 1401/07/27

**Ethics committee reference number**

IR.SUMS.DENTAL.REC.1401.108

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

enamel and dentin erosion

**ICD-10 code**

K03.2

**ICD-10 code description**

Erosion of teeth

## Primary outcomes

### 1

#### Description

Surface microhardness, roughness and surface wear

#### Timepoint

5 days after the erosive/abrasive challenge

#### Method of measurement

Measuring surface wear with contact profilometry, surface hardness using Vickers test, surface roughness with atomic force microscope

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The first intervention group (positive control): using Elmex® erosion protection toothpaste (GABA International AG, Therwil, Switzerland) containing 3500 ppm of tin ions in the form of tin chloride and 1400 ppm of fluoride ions with pH = 4.5. followed by Elmex® erosion protection mouthwash containing 800 ppm of tin ions in the form of tin chloride and 500 ppm of fluoride ions with pH = 4.5. The second intervention group: using Vitis® anticaries toothpaste with nanorepair (VITIS Oral HealthC/O Dent- O-Care, London, UK) containing 1450 ppm fluoride ions in sodium monofluorophosphate, 0.45% nanohydroxyapatite and 10% xylitol. Then using Vitis® anticaries mouthwash containing 1450 ppm fluoride ions in sodium monofluorophosphate, 0.45% nanohydroxyapatite and 10% xylitol.

#### Category

Prevention

### 2

#### Description

Control group: In this group, distilled water is used (appliance without using toothpaste).

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz dental school

##### Full name of responsible person

Dr. Mahtab Memarpour

##### Street address

Dental school, Gasrdasht Street, Shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

15878- 71956

##### Phone

+98 71 3626 3193

##### Email

dental@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Mahtab Memarpour

##### Street address

Dental school, Gasrdasht Street, Shiraz

##### City

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##### Province

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memarpour@sums.ac.ir

#### Grant name

Vice Chancellery of Research of Shiraz University of Medical Sciences

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Shiraz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mahtab Memarpour

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

**Street address**

Dental school, Ghomabad, Ghasrodasht

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mahtab Memarpour

**Position**

Professor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mahtab Memarpour

**Position**

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**Latest degree**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information exists

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable