

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A comparison of white spot lesion prevention of ReminPro, CPP-ACP, MI Paste Plus and fluoride varnish in fixed orthodontic patients

#### Protocol summary

##### Study aim

A comparison of white spot lesion prevention of ReminPro, CPP-ACP, MI Paste Plus and fluoride varnish in fixed orthodontic patients

##### Design

Randomized (random block method), Single-blind, without placebo-controlled, single arm trial. The sample size of this study is 100 individuals: divided into 5 groups of 20 people.

##### Settings and conduct

Private dentistry office.

##### Participants/Inclusion and exclusion criteria

Patients undergoing fixed orthodontic treatment in two jaws. Inclusion criteria: Male and female in age range 12-35 years; no sensitivity to milk protein and benzovate preservers. Exclusion criteria: Less than 6 months have remained to the end of orthodontic treatment; mental/physical disabilities; drug/alcohol addiction; systemic diseases; syndromic disorders.

##### Intervention groups

Control group: Toothbrush, Toothpaste, and Mouthwash  
Intervention group 1: Toothbrush, Toothpaste, and Mouthwash + CPP-ACP  
Intervention group 2: Toothbrush, Toothpaste, and Mouthwash + MI-Paste  
Intervention group 3: toothbrush, toothpaste, and mouthwash + varnish fluoride  
Intervention group 4: Toothbrush, toothpaste, and mouthwash + Remin pro

##### Main outcome variables

White spot lesion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170828035946N2**

Registration date: **2018-06-16, 1397/03/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-16, 1397/03/26**

Update count: **0**

##### Registration date

2018-06-16, 1397/03/26

##### Registrant information

###### Name

Sara Kaveh

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3333 4657

###### Email address

sara.kaveh@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Received fund of Semnan University of Medical Sciences

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-07-21, 1397/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparison of white spot lesion prevention of ReminPro, CPP-ACP, MI Paste Plus and fluoride varnish in fixed orthodontic patients

##### Public title

A comparison of three different mineralization agents on initial tooth caries

##### Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Male and female in age range 12-35 years No sensitivity to milk protein and benzovot preservers

### Exclusion criteria:

Less than 6 months is remained to the end of orthodontic treatment Mental/physical disabilities Drug/alcohol addiction Systemic diseases Syndromic disorders

## Age

From **12 years** old to **35 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization method: randomized blocks. Random unit: Individual. Randomization Tool: Table of random numbers.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Patients will be unaware of the treatment group and placebo.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

##### Street address

5 km of Semnan-Mashhad road, Semnan

##### City

Semnan

##### Province

Semnan

##### Postal code

3514799442

#### Approval date

2017-09-23, 1396/07/01

#### Ethics committee reference number

IR.SEMUMS.REC.1396.5

## Health conditions studied

### 1

#### Description of health condition studied

White spot lesions

#### ICD-10 code

K02.8

#### ICD-10 code description

Other dental caries

## Primary outcomes

### 1

#### Description

White spot lesion

#### Timepoint

2months

#### Method of measurement

Clinical observation based on ICDAS measure

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: Dental floss, Toothbrush, Toothpaste(Darougar Co., Tehran, Iran) and Sodium Fluoride 0.2% Mouthwash(Behsa Co., Tehran, Iran) /flossing and tooth brushing twice a day and mouthwash twice a week

#### Category

Diagnosis

### 2

#### Description

Intervention group 1: Dental floss, Toothbrush, Toothpaste(Darougar Co., Tehran, Iran.) plus CPP-ACP(GC tooth mousse, GC, Tokyo, Japan) /flossing and tooth brushing twice a day and tooth mousse once a night after brushing on teeth by a swab

#### Category

Treatment - Devices

### 3

#### Description

Intervention group 2: Dental floss, Toothbrush, Toothpaste(Darougar Co., Tehran, Iran) plus CPP-ACPF(MI paste, GC, Tokyo, Japan) /flossing and tooth brushing twice a day and MI paste once a night after brushing on teeth by a swab

#### Category

Treatment - Devices

#### 4

##### **Description**

Intervention group 3: Dental floss, Toothbrush, Toothpaste (Darougar Co., Tehran, Iran) plus varnish fluoride (Duraflor, Medicom, Canada) / flossing and tooth brushing twice a day and Fluoride varnish every 2 months

##### **Category**

Treatment - Devices

#### 5

##### **Description**

Intervention group 4: Dental floss, Toothbrush, Toothpaste (Darougar Co., Tehran, Iran) plus Remin pro (Voco, Cuxhaven, Germany) / flossing and tooth brushing twice a day and Remin pro once a night after brushing on teeth by a swab

##### **Category**

Treatment - Devices

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Private dental office

###### **Full name of responsible person**

Sara Kaveh

###### **Street address**

Shahrivar Blvd, Semnan

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###### **Phone**

+98 23 3346 1336

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sara.kaveh@semums.ac.ir

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Semnan University of Medical Sciences

###### **Full name of responsible person**

Mohammadreza Asgari

###### **Street address**

Semnan University of Medical Sciences, Basij Boulevard, Semnan

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asgari5000@gmail.com

###### **Grant name**

###### **Grant code / Reference number**

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

Yes

###### **Title of funding source**

Semnan 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**

Semnan University of Medical Sciences

###### **Full name of responsible person**

Sara Kaveh

###### **Position**

Associate professor

###### **Latest degree**

Specialist

###### **Other areas of specialty/work**

Dentistry

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### **Person responsible for scientific inquiries**

##### **Contact**

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###### **Full name of responsible person**

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###### **Position**

Assistant professor

###### **Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Position**  
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Semnan  
**Postal code**

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### Phone

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### Email

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### 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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

-

### When the data will become available and for how long

-

### To whom data/document is available

Only available to scholars working in academic institutions.

### Under which criteria data/document could be used

In case of relevant studies.

### From where data/document is obtainable

Sara Kaveh, Shahrivar Blvd, Semnan, +98 933 380 0959

### What processes are involved for a request to access data/document

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### Comments