

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

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3346 1336

Email

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

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3346 1336

Email

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

Street address

Faculty of Dentistry, Saadi Square, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3346 1336

Fax

Email

sara.kaveh.ir@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Sara Kaveh

Position

Assistant professor

Latest degree

Specialist
Other areas of specialty/work
Dentistry
Street address
Faculty of Dentistry, Saadi Square, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3346 1336
Fax
Email
sara.kaveh.ir@gmail.com
Web page address

Person responsible for updating data

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
Street address
Faculty of Dentistry, Saadi Square, Semnan
City
Semnan
Province
Semnan
Postal code

3514799442
Phone
+98 23 3346 1336
Email
sara.kaveh.ir@gmail.com

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

-

Comments