Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 benzovat 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)

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+98 23 3333 4657

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sara.kaveh@semums.ac.ir

Recruitment status
Recruitment complete

Funding source
Received fond of Semnan University of Mdical 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 benzovat 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 Flouride 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 brushig 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
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Shahrivar Blvd, Semnan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mohammadreza Asgari
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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
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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
-

Comments