Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of pH changes in orthodontic patients using Casein Phosphopeptide -Amorphous Calcium Phosphate with Fluoride paste

Protocol summary

Summary

The aim of this study was to investigate the effect of Casein Phosphopeptide -Amorphous Calcium Phosphate with Fluoride paste on plaque and salivary pH levels in fixed orthodontic patients. In this crossover randomized clinical trial, performed in a private practice, 30 patients who have undergone fixed orthodontic treatment for at least 3 and at most 12 months, free from systemic disorders, not using any medication or mouthwash and have maintained permanent first molars were included in this study. The initial plaque and salivary pH is recorded and then patients are randomly assigned to 2 groups, where in the first group patients are instructed to use a Casein Phosphopeptide -Amorphous Calcium Phosphate/Fluoride paste and a placebo in the other. The pH levels are recorded after one month, where after patients experience a one month washout period. The pH is recorded once again and the patients are given the alternative paste respectively. The final pH levels are recorded after one month of using the alternate paste. In this study, the clinician, researcher and patient are blinded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903244185N1**
Registration date: **2011-07-12, 1390/04/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-12, 1390/04/21

Registrant information

Name
Haleh Heshmat
Name of organization / entity
Islamic Azad University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2010-12-21, 1389/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of pH changes in orthodontic patients using Casein Phosphopeptide -Amorphous Calcium Phosphate with Fluoride paste

Public title

Investigating the effect of Casein Phosphopeptide - Amorphous Calcium Phosphate with Fluoride on caries prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Patients receiving fixed orthodontic

treatment and over 12 years of age. Between 3 and 12 months of their orthodontic treatment should have commenced. Exclusion criteria: Taking medications; systemic diseases; pregnancy; loss/missing of first permanent molars; using mouthwashes.

Age
From **12 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Dentistry Ethics comittee, Tehran Islamic Azad University

Street address
No.4 - Neyestan 10 - Pasdaran Street

City
Tehran

Postal code

Approval date
2011-03-13, 1389/12/22

Ethics committee reference number
پ/129/د

Health conditions studied

1

Description of health condition studied
Caries limited to enamel

ICD-10 code
K02.0

ICD-10 code description
White spots (Initial caries)

Primary outcomes

1

Description
Salivary pH

Timepoint
Before and after each paste use. A total of 4 measures with one month intervals

Method of measurement
pH test strips

2

Description
Plaque pH

Timepoint
Before and after each paste use. A total of 4 measures with one month intervals

Method of measurement
pH test strips

Secondary outcomes

empty

Intervention groups

1

Description
As a crossover study, patients in the first group receive the medication - MI paste plus - containing casein phosphopeptide - amorphous calcium phosphate and Fluoride. A pea-sized amount of the paste is applied to the teeth each night after routine brushing. This regimen is continued for one month

Category
Treatment - Drugs

2

Description
As a crossover study, patients in the second group receive the placebo paste first. The placebo is also a paste but devoid of any active ingredient. A pea-sized amount of the paste is applied to the teeth each night after routine brushing. This regimen is continued for one month.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Private practice

Full name of responsible person
Faramarz Mojtahedzadeh DMD, MS

Street address

No. 3, 8th street, Gandhi Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Haleh Heshmat

Street address

2D, Building 12, Sina Complex, Iranzamin St, Phase 1, Shahrake Qarb

City

Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Investigator

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

School of Dentistry, Tehran Azad University

Full name of responsible person

Haleh Heshmat DMD,MS

Position

Specialist in Restorative Dentistry/ Assistant Professor

Other areas of specialty/work

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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