Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Green Tea Extract and Casein Phosphopeptide- Amorphous Calcium Phosphate (CPP-ACP) effect on white spot recovery in retention phase of fixed orthodontic treatment: A Triple-Blind Randomized Clinical Trial

Protocol summary

Study aim
This study evaluates whether the orthodontic retention phase can be used not only for tooth stabilization but also for treating white spot lesions, comparing green tea extract with CPP-ACP as a more accessible natural option.

Design
A randomized, triple-blind, parallel-group, controlled Phase 3 clinical trial conducted on 36 teeth in each intervention group (the study includes two intervention groups). Randomization will be performed using a random numbers table.

Settings and conduct
This study will be performed in clinics affiliated with Isfahan University of Medical Sciences, including the TorabiNejad, Ghaedi, and Afzal clinics. Each patient receives two syringes: one contains CPP-ACP or green tea and one placebo, applied nightly to the reservoir spaces. Lesions are measured with a DIAGNOdent Pen at baseline, 1 month, and 2 months. The study is triple-blinded (patient, operator, and statistician). Randomizing the distribution of the sample is done using a random number table.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 15 to 30 years; Presence of at least one white spot lesion with a DIAGNOdent score between 10 and 20 on the corresponding teeth on both sides of one arch. Exclusion criteria: Systemic diseases, Tooth rotation, gingival hyperplasia, and tobacco use.

Intervention groups
Intervention group Includes two subgroups of 36 teeth each with white spot lesions (DIAGNOdent 10–20). These teeth are treated with either green tea extract or CPP-ACP paste. Comparison group Includes two corresponding subgroups of 36 contralateral teeth with the same DIAGNOdent range (10–20). These teeth receive a placebo.

Main outcome variables
WSLs remineralization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260417069084N1**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**
Update count: **1**

Registration date
2026-04-22, 1405/02/02

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-21, 1405/02/31

Expected recruitment end date
2026-06-21, 1405/03/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Green Tea Extract and Casein Phosphopeptide- Amorphous Calcium Phosphate (CPP-ACP) effect on white spot recovery in retention phase of fixed orthodontic treatment: A Triple-Blind Randomized Clinical Trial

Public title
Evaluation of Green Tea Extract and CPP-ACP effect on white spots
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is aged between 15 and 30 years Initiation of the retention phase following fixed orthodontic treatment with the prescription of an Essix retainer for at least one arch Presence of at least one and at most five inactive enamel white-spot lesions with a maximum size of 4 mm and a DIAGNOdent score between 10 and 20 located on the labial or lingual surfaces of corresponding teeth on both sides of the same arch The individual must have the willingness and mental/physical ability to maintain proper oral hygiene and cooperate throughout the study
Exclusion criteria:
Systemic diseases affecting oral tissues or salivary quality Severe tooth rotation prior to orthodontic treatment Gingival hyperplasia or severe inflammation Tobacco use or use of anti-caries products The patient with DMFT score higher than 8 (High Risk)
Age
From **15 years** old to **30 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
More than 1 sample in each individual
Number of samples in each individual: **10**
An inactive white spot lesion, with a maximum size of 4 millimeters and a Diagnodent score between 10 and 20, on the labial or lingual surfaces of corresponding teeth on both sides of the same arch
Randomization (investigator's opinion)
Randomized
Randomization description
The study for each ingredient will be conducted in a split-mouth design. Considering the differences in individuals' brushing patterns on the dominant and non-dominant side (depending on right- or left-handedness), and the potential differences in oral hygiene accuracy and fluoride exposure between the two sides of the jaw, the number of teeth receiving the intervention on the dominant side will also be kept equal. Therefore, Group 1 will include 36 teeth (18 pairs), in which 18 teeth on the dominant side (according to right- or left-handedness) will receive green tea extract and the contralateral teeth will receive placebo. Another 18 teeth on the non-dominant side will receive green tea extract and the opposite teeth will receive placebo. Group 2 will include 36 teeth (18 pairs), in which 18 teeth on the dominant side will receive CPP-ACP paste and the contralateral teeth will receive placebo. Another 18 teeth on the non-dominant side will receive CPP-ACP paste and the opposite teeth will receive placebo. Randomization of sample allocation will be performed using simple randomization based on a random number table.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient is given two syringes, one containing the intervention material (CPP-ACP or green tea) and the other containing a placebo. The patient is unaware of which syringe contains the active material or the placebo. During the evaluation; after one and two months, the assessment is performed by a second investigator who is blinded to the side of the intervention. During data analysis as well, the statistical analyst will have no information regarding the type of intervention used in the patients' mouths or the side on which it was applied. Therefore, the study will be triple-blind, and the patient, the intervention provider, and the statistical analyst will all be unaware of the type of material used for application, delivery to the patients, or the assessment and analysis of remineralization.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
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School of Dentistry, Isfahan University of Medical Sciences and Health Services, Hezarjerib Street
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Postal code
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Approval date
2026-04-11, 1405/01/22

Ethics committee reference number
IR.MUI.DHMT.REC.1405.006

Health conditions studied

1

Description of health condition studied
White Spot Lesions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
WSLs Remineralization Score Measured By DIAGNOdent Pen

Timepoint
Baseline, one month, two months

Method of measurement
DIAGNOdent Pen

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Green Tea Extract

Category
Treatment - Drugs

2

Description
Intervention group: Casein Phosphopeptide-Amorphous Calcium Phosphate

Category
Treatment - Drugs

3

Description
Control group: Placebo

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Torabinejad Dental Clinic

Full name of responsible person
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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
Esfahan 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

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Amin Ansarinia
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
In addition to the main information containing the primary outcome, other necessary information, such as demographic data, the level of participant cooperation and... can also be published if necessary, provided that no personally identifiable information is disclosed.
When the data will become available and for how long
The access period begins 3 months after the publication of the results.
To whom data/document is available
Provided that all participants' rights in the study are fully respected and their contact or identifying information is not disclosed, it is possible to share their non-private data with all academic or non-academic researchers, as well as pharmaceutical development companies.
Under which criteria data/document could be used
The data are shared solely to make the study more transparent and to allow their use for research purposes as well as for development and production activities in pharmaceutical companies and similar organizations.
From where data/document is obtainable
For this purpose, requests should be sent to the email address of the corresponding author. The corresponding author's email address is: parnianrdi2@gmail.com
What processes are involved for a request to access data/document
The applicant must clearly state the reasons for requesting additional information and acknowledge that only non-private participant data can be provided. After submitting the request, the applicant should allow up to two weeks for the required information to be delivered.
Comments