Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effect of nano hydroxyapatites serum and two different finishing, polishing techniques on reduction of enamel staining after orthodontic debonding in comprehensive orthodontic patients; a randomized clinical trial.

Protocol summary

Summary

Orthodontic treatment can lead to adverse effects on enamel surfaces, which are manifested as enamel loss caused by etching, enamel surface alterations and micro cracks and scratches, induced during debonding and clean up procedures. In addition to these obvious factors, the abrasion of the enamel surface caused by post orthodontic debonding and clean up procedures could result in more color absorption. In this study, twenty orthodontic patients with non extraction orthodontic treatment and acceptable hygiene will be evaluated for enamel staining after orthodontic debonding. There are two variables for this randomized clinical trial: ten days application of Nano Hydroxyapatite on enamel surface during the first ten days after debonding, and different polishing techniques at resin removal stage in debonding procedures. The usage of carbide bur alone, as the conventional method, and the combination use of carbide burs and Soflex disks will be compared to each other. The enamel staining will be evaluated by reflectance spectrophotometer in 3 periods: immediately after debonding, two, and finally, four months after debonding. The aim of this study is to assess the effect of Nano Hydroxyapatite serum and different finishing, polishing techniques on color alterations of enamel that has been influenced by debonding procedures after comprehensive orthodontic treatment, by employing a spectrophotometer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052628092N1**
Registration date: **2017-10-31, 1396/08/09**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-10-31, 1396/08/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-07-21, 1396/04/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of nano hydroxyapatites serum and two different finishing, polishing techniques on reduction of enamel staining after orthodontic debonding in comprehensive orthodontic patients; a randomized clinical trial.

Public title
Evaluation of the effect of nano hydroxyapatites serum on reduction of enamel staining after orthodontic debonding with two different finishing, polishing techniques.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: adult patients (18 to 25 years old); patients with good compliance for this trial; permanent dentition; no plaque accumulation; Gingival and Plaque Index of 0 to 1; absence of dental caries and decalcifications in the teeth under examination; no smoking habit; non extraction orthodontic treatment.
Exclusion criteria: patients with poor compliance; patients that had extraction in their orthodontic treatment; smokers; presence of caries or decalcifications in the teeth under examination; primary or mixed dentition; plaque accumulation; Gingival and Plaque Index more than 1.

Age
From **18 years** old to **25 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Postcode: 71345-1978, Central building of Shiraz University of Medical Sciences, Zand street, Shiraz, Iran

City
Shiraz

Postal code

Approval date
2017-07-09, 1396/04/18

Ethics committee reference number
IR.SUMS.REC.1396.69

Health conditions studied

1

Description of health condition studied
Effect of nano hydroxyapatites serum on reduction of enamel staining after orthodontic debonding with two different finishing, polishing techniques.

ICD-10 code
k03.7

ICD-10 code description
Posteruptive colour changes of dental hard tissues

Primary outcomes

1

Description
Enamel staining

Timepoint
Before intervention, 2 months after intervention, 4 months after intervention

Method of measurement
Measurement of tooth color parameters

Secondary outcomes

empty

Intervention groups

1

Description
At the end of the fixed orthodontic treatment, brackets will be detached using a hand plier by gently squeezing the mesial and distal wings together. Removal of remnant resin will be done on all teeth by means of using carbide burs operated with low speed and water cooling used for 20 seconds. Then, randomly on one side of the mouth (Intervention group), carbide burs, followed by aluminum oxide discs (SofLex), will be used on the upper and lower premolars for finishing procedure. Randomization will be done by coin tossing. Then a rubber cup will be used in order to polish all teeth. All procedures will be performed by a single clinician and a new bur and rubber cup and disc will be used for each patient. To ensure complete resin removal, teeth will be evaluated under dental operating light with dental explorer. For all patients, the Nano Hydroxyapatite (Nano HAP) serum will be applied on the upper left and right first and second premolars (Intervention group), and the color alterations will be compared with lower left and right first and second premolars. Instruction for application of Nano HAP serum is as follows: a high concentration Nano HAP serum will be applied by the clinician on the teeth surface daily for 10 days, with a sponge on the head of the Nano HAP tubes for 2 to 3 minutes, and rinsed after 20 minutes with water. During

the application of the solution, the teeth will be isolated with cotton rolls, according to the manufacturer's instructions. A timetable will be given to the patients to control oral hygiene at home.

Category
Prevention

2

Description
At the end of the fixed orthodontic treatment, brackets will be detached using a hand plier by gently squeezing the mesial and distal wings together. On the other side of the mouth, (Control group) after removal of the remnant resin by means of carbide burs, SofLex discs will not be used, just a rubber cup will be used in order to polish teeth. All procedures will be performed by single clinician and a new bur and rubber cup will be used for each patient. To ensure complete resin removal, teeth will be evaluated under dental operating light with dental explorer. The Nano HAP serum will not be applied on the lower left and right first and second premolars (control group), and the color alterations will be compared with the upper left and right first and second premolars. In order to optimize the results, the incisal third of the buccal surface of central incisors which is not affected by bonding and debonding procedures, is considered as the negative control group and will be evaluated by spectrophotometry analysis like other groups.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Postgraduate Clinic, Department of Orthodontics, School of Dentistry
Full name of responsible person
Street address
City
shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Shabnam Ajami
Street address
Postcode: 71345-1836, Shiraz Dental School, Ghom abad, Ghasrodasht street, Shiraz, Iran
City
shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
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
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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