Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of toothpaste containing Bioactiveglass in remineralization of white spot lesion during fixed orthodontic treatment: A randomized clinical trial

Protocol summary

Study aim
To determine the effect of toothpaste containing bioactive glass on remineralization of white enamel lesions during orthodontic treatment.

Design
This study is a three-blind controlled randomized clinical trial with parallel groups on 38 patients using block randomization method.

Settings and conduct
This study is performed in the orthodontic department of Hamadan Dental School. At the initial visit, patients receive instructions for hygiene twice daily use of toothpaste For each patient, the most severe white enamel lesion with the highest number of Diagnodent is evaluated and is evaluated by DIAGNOdent at the beginning, after one month and after three months. All tubes of toothpaste are covered by a blinding label. At the beginning of the study, a random number code is assigned to each patient And the researcher who makes the measurements and the statistical analyzer are blind

Participants/Inclusion and exclusion criteria
Inclusion criteria are: fixed orthodontic appellation on all teeth, remaining at least 3 months until the end of orthodontic treatment, having at least one white enamel lesion on the buccal surface of six anterior teeth and the first premolars in the upper or lower jaw. Exclusion criteria are: Oral or medical diseases

Intervention groups
Intervention group: Receiving toothpaste containing bioactive glass and using it twice a day for 3 months - Control group: Receiving toothpaste containing fluoride and using it twice a day for 3 months Comparison of the effectiveness of bioactive glass in comparison with fluoride in improving the condition of primary enamel caries

Main outcome variables
Improves the remineralization rate of lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140215016582N5**
Registration date: **2021-01-24, 1399/11/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-24, 1399/11/05**
Update count: **0**

Registration date
2021-01-24, 1399/11/05

Registrant information

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Vahid Mollabashi

Name of organization / entity
Hamadan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of toothpaste containing Bioactiveglass in remineralization of white spot lesion during fixed orthodontic treatment: A randomized clinical trial

Public title
The effect of bioactive glass toothpaste on improving the early stages of dental caries during fixed orthodontic treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Fixed orthodontic applique on all teeth Remain at least 3 months until the end of fixed orthodontic treatment Having at least one white enamel lesion on the buccal surface of six anterior teeth and the first premolars in the maxilla or mandible

Exclusion criteria:
Active dental caries Active periodontal disease Teeth with enamel defects Teeth with internal and external discoloration such as fluorosis or tetracycline discoloration Primary teeth Facial-oral syndromes and cleft lip and palatal deformity Patients under medical treatment or patients taking any type of medication

Age
From **15 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the block quantification method, it is divided into control group and study group by the researcher. The method of confiscation is that four blocks are used. If there are two treatments A and B, there are six different blocks as AABB, BBAA, ABAB, BABA, ABBA and BAAB. Random numbers between zero and one are now generated and the blocks are randomly selected based on random numbers. Thus, for numbers between 0 and 0.17, the first block, for numbers between 0.18 and 0.33, and the second block, for numbers between 0.34 and

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, patients are aware of the purpose of the study, which is to control white enamel lesions, but are blind to the product to be used in the study or to the group to which they belong. All tubes are covered by a blinding label. Assessments at all appointments are performed by an independent researcher who is blind to the groups. Statistical analysis is performed by a researcher who is blind to treatments.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Science

Street address
Shahid Fahmide Ave,

City
Hamadan

Province
Hamadan

Postal code
654178-38741

Approval date
2020-12-14, 1399/09/24

Ethics committee reference number
IR.UMSHA.REC.1399.763

Health conditions studied

1

Description of health condition studied
Enamel white lesions

ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
Change in white enamel lesions

Timepoint
At the beginning of the study and one month later and three months later

Method of measurement
Diagnodent laser device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving toothpaste containing bioactive glass. In this group, the amount of tooth mineralization is first determined using a diagnostic laser made by the German company Kavo. Patients are then given toothpaste containing the bioactive glass (sensodyne, powered by Novamin) in a white tube without specifications and patients are instructed twice a day with a certain amount of toothpaste (about the size of a pea) for Brush their teeth for two minutes in 3 months. The amount of mineralization of the tooth is measured by the diagnostic device one and three months later

Category

Treatment - Other

2

Description

Control group: Patients receiving fluoride toothpaste. In this group, the amount of tooth mineralization is first determined using a diagnostic laser made by the German company Kavo. Fluoride toothpaste (sensodyne, Rapid Relief) is then given to patients in a white tube without specifications and patients are instructed to take a certain amount of toothpaste (about the size of a pea) twice a day for two minutes. Brush their teeth for 3 months. The amount of mineralization of the tooth is measured by the diagnostic device one and three months later

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Orthodontics, Hamadan Dental School
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Maryam Heydarpour
Position
Resident
Latest degree
Medical doctor
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

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

Yes - There is a plan to make this available

Title and more details about the data/document

Individual data includes demographic characteristics and original outcome information are shared

When the data will become available and for how long

Start the access period starts 6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutes and companies producing toothpaste

Under which criteria data/document could be used

Unidentifiable information will not be provided due to the type of consent given to patients and the obligation of the investigator to comply with ethical requirements.

From where data/document is obtainable

Maryam Haidarpour: corresponding author, Maryamheydarpour @ gmail.com Vahid Malabashi: First author, mollabashi@umsha.ac.ir

What processes are involved for a request to access data/document

After result publication through electronic E Mail of corresponding author and complete introduction and mention the goal from having the documentation, within a maximum one week related file is available to the applicant

Comments