

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 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 appliance 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

Name

Vahid Mollabashi

Name of organization / entity

Hamadan University of Medical Sciences

Country

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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

Maryam Heydarpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeed Bashirian

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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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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Position

Resident

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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