

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of microhardness and surface chemical characteristics of dental varnish fortified with nano-bioactive glass contains Strontium and Cobalt on permanent tooth:a clinical trial

Protocol summary

Study aim

Comparison of microhardness and surface chemical characteristics of dental varnish reinforced with nano-bioactive glass containing strontium and cobalt in intervention and control groups

Design

The intervention and control groups are determined in random manner using random numbers. The sample is 21 and blinding will be done and the effect of the intervention will be checked after 4 weeks.

Settings and conduct

The present clinical trial study will be conducted in Hamedan Faculty and in a simple random manner on patients who are undergoing orthodontic treatment. The teeth are numbered with a table of random numbers. The teeth of the intervention group will receive varnish, but the teeth of the control group will be dipped in distilled water to blind the patient. After 4 weeks when teeth are extracted microhardness and chemostructural properties are checked

Participants/Inclusion and exclusion criteria

Teeth can be included in our study that have a counterpart tooth on the opposite side and need to be pulled. The buccal surface of the mentioned teeth should be healthy and not have much decay

Intervention groups

Two premolar teeth of people who need to have their premolar teeth extracted due to orthodontics are used as a study sample. Fluoride varnish reinforced with nano-bioactive glass containing strontium and cobalt is applied to one of the premolar teeth with the corresponding tooth on the opposite side, and the other tooth receives distilled water. After 4 weeks from the beginning of the study, the aforementioned teeth are extracted and examined in laboratory conditions for microhardness and chemical surface characteristics.

Main outcome variables

Comparison of microhardness in the intervention and control group.; Comparison of chemostructural properties in the intervention and control group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054642N1**

Registration date: **2022-10-29, 1401/08/07**

Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**

Update count: **0**

Registration date

2022-10-29, 1401/08/07

Registrant information

Name

shaghayegh golshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3334 6323

Email address

sh.golshani@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-05, 1401/09/14

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of microhardness and surface chemical characteristics of dental varnish fortified with nano-bioactive glass contains Strontium and Cobalt on permanent tooth:a clinical trial

Public title

Investigating the effects of reinforced dental varnish containing strontium and cobalt on permanent teeth

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Two similar teeth in one person need to be extracted

Exclusion criteria:

The crowns of the teeth that need to be extracted have decay on the buccal surface

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **21**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two premolar teeth of people who need to have their premolar teeth extracted due to orthodontics are used as a study sample. Fluoride varnish reinforced with nano-bioactive glass containing strontium and cobalt is applied to one of the premolar teeth with the corresponding tooth on the opposite side, and the other tooth does not receive that substance.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in a simple way with the help of a table of random numbers. For each even number, code A is assigned to apply varnish on the right premolar tooth, and for each odd number, code B is assigned to apply varnish to the left premolar tooth. Finally, a random chain of 21 letters A and B is formed with a random sequence. Cards A and B will be placed in the envelopes with numbers 1 to 21 in the order obtained, and upon the arrival of each patient who is eligible for the study, the corresponding envelope will be opened and the treatment group for that patient will be determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The teeth of the control group, which does not need to receive a substance, are dipped in distilled water to blind

the participant, while the teeth of the intervention group receive varnish.

Placebo

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 Sciences

Street address

Hamedan, Pajhoohesh intersection, Shahid Fahmideh St., in front of Mardom Park, Faculty of Dentistry, Children's Department

City

hamadan

Province

Hamadan

Postal code

6517838677

Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.UMSHA.REC.1401.473

Health conditions studied**1****Description of health condition studied**

dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes**1****Description**

surface chemical characteristics of teeth

Timepoint

The characteristics will be measured only once in each intervention and control group after the extraction of the teeth and their mounts, thus it will be done at least 4 weeks after the start of the study.

Method of measurement

Raman test

2

Description

microhardness of teeth

Timepoint

The characteristics will be measured only once in each intervention and control group after the extraction of the teeth and their mounts, thus it will be done at least 4 weeks after the start of the study.

Method of measurement

vickers test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: recipient of dental varnish reinforced with nano-bioactive glass containing strontium and cobalt on the buccal surface of premolar teeth. Both premolar teeth in the intervention and control groups were extracted after 4 weeks

Category

Prevention

2

Description

Control group: without receiving varnish on the premolar tooth, which receives distilled water for blinding. Both premolar teeth in the intervention and control groups were extracted after 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Department of Hamadan Dental School

Full name of responsible person

Shaghayegh Golshani

Street address

Hamedan, Shahid Fahmideh Street, Hamadan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Shaghayegh Golshani

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Grant name

Grant code / Reference number

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

No

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

Shaghayegh Golshani

Position

Post-graduated student

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

After extraction, the studied teeth are measured for microhardness and surface chemical characteristics. This data can be shared after de-identifying individuals.

When the data will become available and for how long

It is expected that the required data will be collected in February 1401 and will be accessible from that date.

To whom data/document is available

Considering that this study will be done in the form of a student thesis, I think it will be available for researchers working in academic institutions.

Under which criteria data/document could be used

We have no limits for this work

From where data/document is obtainable

I, Shaghaig Golshani, will be available to provide documentation sh.golshani@edu.umsha.ac.ir

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

The applicant should describe the reason for the need for our study documents along with her complete introduction, and I will respond to her via email if I deem it appropriate.

Comments