

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of anti-Bacterial effect of dental varnish fortified with nano-bioactive glass contains Strontium and Cobalt on permanent tooth: A clinical trial

Protocol summary

Study aim

Comparison of the number of mutans bacteria in the intervention group (containing dental varnish with nano-bioactive glass containing strontium and cobalt) and the control group (without receiving varnish)

Design

Clinical trial with two intervention and control groups in parallel and random assignment, blinded

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. In the first session, the diagnostic pen and microbial plaque are recorded. 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, diagenodent pen and microbial plaque 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 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 any substance. After 4 weeks, the mentioned teeth are checked, the microbial plaque on the tooth is removed. teeth will be extracted and examined conditions for antibacterial properties.

Main outcome variables

Comparison of mutans bacteria in 2 groups at the

beginning of the study; Comparison of the number of mutans bacteria in the intervention group at the beginning of the study and after 4 weeks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054642N2**

Registration date: **2022-10-31, 1401/08/09**

Registration timing: **prospective**

Last update: **2022-10-31, 1401/08/09**

Update count: **0**

Registration date

2022-10-31, 1401/08/09

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

2022-12-03, 1401/09/12

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 anti-Bacterial effect of dental varnish fortified with nano-bioactive glass contains Strontium and Cobalt on permanent tooth: A clinical trial

Public title

Evaluation of anti-Bacterial effect of dental varnish fortified with nano-bioactive glass contains Strontium and Cobalt

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

0

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 any 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

In order to blind the participant, according to the assigned treatment group, in addition to applying varnish

on the premolar tooth of the corresponding side, the same treatment method with distilled water will be applied to the corresponding premolar tooth of the opposite side.

Placebo

Not used

Assignment

Single

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, Chaharrah-e-Khoresh, Shahid Fahmideh St., in front of Mardom Park, Faculty of Dentistry, Children's Department

City

Hamadan

Province

Hamadan

Postal code

6517838677

Approval date

2022-08-21, 1401/05/30

Ethics committee reference number

IR.UMSHA.REC.1401.458

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

Dental caries

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Antimicrobial properties of teeth

Timepoint

4 weeks

Method of measurement

Counting the number of mutans bacteria

Secondary outcomes

1

Description

the number which is obtained by diagnodent pen

Timepoint

The effect of varnish on the number obtained from the Diagnodent pen at the beginning of the study and after 4 weeks

Method of measurement

Diagnodent laser pen

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: 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

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Department of Hamadan Dental School

Full name of responsible person

Shaghayegh Golshani

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Hamedan, Shahid Fahmideh Street, Hamadan Crossroads, Faculty of Dentistry, Children's Department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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

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 the number of mutans streptococci. 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