Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, diagnodent 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 Hamشdan 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
Street address
Hamedan, Shahid Fahmideh Street, Hamadan Crossroads, Faculty of Dentistry, Children's Department
City
Hamadan
Province
Hamadan
Postal code
6517838677
Phone
+98 919 385 4020
Email
sh.golshani@edu.umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Shaghyegh Golshani
Street address
Hamedan, Shahid Fahmideh Street, Hamadan Crossroads, Faculty of Dentistry, Children's Department
City
hamadan
Province
Hamadan
Postal code
6517838677
Phone
+98 919 385 4020
Email
sh.golshani@edu.umsha.ac.ir
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
Street address
Hamadan,roohani street,blook131,third floor
City
Hamedan
Province
Hamadan
Postal code
6517838677
Phone
+98 81 3838 1059

Fax
Email
sh.golshani@edu.umsha.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Shaghayegh Golshani
Position
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Province
Hamadan
Postal code
6517838677
Phone
+98 81 3838 1059
Fax
Email
sh.golshani@edu.umsha.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Shaghayegh Golshani
Position
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Fax
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sh.golshani@edu.umsha.ac.ir

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