Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of microhardness and surface chemical charactristics 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 charactristics 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 charactristics 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 Crossroads, Faculty of Dentistry, Children's Department
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Sponsors / Funding sources

1

Sponsor
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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?
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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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 charactristics 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