

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation and comparison of the effects of a new paste containing 8% L-Arginine and CaCO₃ plus KNO₃ on dentinal tubules occlusion and dental sensitivity: a randomized, triangular blinded clinical trial study

Protocol summary

Study aim

Evaluation of the effect of a new paste containing L-arginine/calcium carbonate 8% and potassium nitrate on the occlusion of dentinal tubules and tooth sensitivity

Design

A clinical trial with a control group, with parallel groups, triple-blind, randomized, phase 3 on 16 patients. For randomization, manual drawing with sealed envelopes was used.

Settings and conduct

This study is conducted in the restorative department of Mashhad Dental School, and the application process is done by one person and the sensitivity assessment is done by another person who is not aware of the type of treatment for each half to blind the patient, evaluator and statistician. To evaluate the sensitivity to cold and touch, a 1 cm air puff was used for 3 seconds and the movement of a probe in the CEJ area were used, respectively.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patients in need of dental desensitization treatment, in such a way that the teeth that need to be desensitized are free of decay or restoration. • Patients with an age range of 18 to 50 years • Patients in good general and oral health conditions • Not having a history of illness or long-term drug use • People who do not use orthodontic appliances
Exclusion criteria: • The patient's unwillingness to continue cooperation • Non-attendance of the patient

Intervention groups

In this study, the intervention means using an anti-sensitive paste formulated on the subjects' sensitive teeth and measuring the tooth sensitivity level before and after the application. The control group is the same person who has used paste without active ingredients on his opposite-side teeth.

Main outcome variables

Dental sensitivity before application; immediately after the application; 24 hours; A week; One month, and three months after the work, as well as the closure of dentin tubules under the microscope 24 hours after the work.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220829055822N1**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Arsalan Shahri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3844 5332

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of the effects of a new paste containing 8% L-Arginine and CaCO₃ plus KNO₃ on dentinal tubules occlusion and dental sensitivity: a randomized, triangular blinded clinical trial study

Public title
Evaluation of an anti sensitivity paste on teeth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

- Patients who need anti-sensitive treatment of teeth without caries
- Patients in good general and oral health conditions
- Not having a history of illness or long-term drug use
- People who do not use orthodontic appliances

Exclusion criteria:

- The patient's unwillingness to continue cooperation
- Non-attendance of the patient during visit sessions

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **16**
More than 1 sample in each individual
Number of samples in each individual: **2**
In the form of split-mouth, each person is both control and intervention

Randomization (investigator's opinion)
Randomized

Randomization description
The method of applying the anti-sensitive paste in this study will be split-mouth, and the choice of the treated half of the jaw as control or intervention will be random, in such a way that each patient randomly chooses the type of treatment for his/her half of the jaw. Each patient receives a sealed envelope of 8 envelopes related to his/her gender group and determines his/her control and intervention half of the jaw.

Blinding (investigator's opinion)
Triple blinded

Blinding description
One person does the application of anti-sensitive paste, and the evaluation of sensitivity is done by another person who is unaware of the type of treatment for each half of the jaw. Also, the patient does not know the contents of the received envelope. Therefore, the patient, evaluator, and statistician are blind to the type

of treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Dentistry - Mashhad University of Medical Sciences

Street address
No.2 , 16th Hakim St. Koohsangi Ave.

City
Mashhad

Province
Razavi Khorasan

Postal code
9175966333

Approval date
2022-04-06, 1401/01/17

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1401.002

Health conditions studied

1

Description of health condition studied
tooth sensitivity, dental sensitivity

ICD-10 code
K08.8

ICD-10 code description
Other specified disorders of teeth and supporting structures

Primary outcomes

1

Description
Dental sensitivity

Timepoint
before work; immediately after the application; 24 hours; A week; One month and three months after application

Method of measurement
For sensitivity to cold, an air-water syringe was used for 3 seconds at a distance of 1 cm from the tooth while isolating the side teeth. For palpation, the movement of the scaler probe was used in the CEJ region of the desired tooth. Finally, the VAS criterion was used to record the results.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the synthesized paste containing the active ingredient L-arginine/calcium carbonate 8% and potassium nitrate 3% was used. 2 times on 2 consecutive days, the paste was applied in the clinic for half an hour. It was refreshed one time during the process every day. A micro brush was used for the application process while isolating the side teeth. Due to the need for saliva and its enzymes, excessive drying of the oral environment was prevented.

Category

Treatment - Drugs

2

Description

Control group: In this group, the synthesized paste without the active ingredient L-arginine/calcium carbonate 8% and potassium nitrate 3% was used. 2 times on 2 consecutive days, the paste was applied in the clinic for half an hour. It was refreshed one time during the process every day. A micro brush was used for the application process while isolating the side teeth. Due to the need for saliva and its enzymes, excessive drying of the oral environment was prevented.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry

Full name of responsible person

Arsalan Shahri

Street address

VakilAbad Blvd. Faculty of Dentistry

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

معاون تحقیقات و فناوری دانشگاه علوم پزشکی مشهد

Street address

Daneshgah St. Central building of University

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13944-91388

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p.relations@mums.ac.ir

Web page address

<https://www.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Arsalan Shahri

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participants: Basic information including name and age and information about the main outcome will be published.

When the data will become available and for how long

The access period starts 1 month after the results are published

To whom data/document is available

Due to the non-confidentiality of the information, its use is free for everyone.

Under which criteria data/document could be used

Due to the non-confidentiality of the information, its use is free for everyone.

From where data/document is obtainable

Arsalan Shahri

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

It will be sent to the applicant within 4 working days.

Comments