

# 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 CaCO<sub>3</sub> plus KNO<sub>3</sub> 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)

##### Phone

+98 51 3844 5332

##### Email address

shahria951@mums.ac.ir

##### 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 CaCO<sub>3</sub> plus KNO<sub>3</sub> 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

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177948909

#### Phone

+98 51 3882 9501

#### Email

web@mums.ac.ir

## 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

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

13944-91388

#### Phone

+98 51 3841 2081

#### Email

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 scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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**Position**  
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**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Arsalan Shahri  
**Position**  
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**Latest degree**  
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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