

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparative evaluation of effectiveness of two toothpastes containing potassium nitrate in the treatment of dentinal hypersensitivity secondary to scaling and root planing

Protocol summary

Study aim

Comparison of the effectiveness of two types of toothpaste containing potassium nitrate in the treatment of dental hypersensitivity secondary to SRP

Design

Clinical trial with 2 groups of parallel intervention, double-blind, randomized, phase 3 on 22 patients, our tool is to randomize the table of random numbers, The sample size in each group is 11 people, and a total of 22 people.

Settings and conduct

This study will be carried out in the Periodontics department of Tabriz dental faculty. The two groups will be assimilated based on age and gender. dental hypersensitivity is determined at the beginning of the period, then on the 15th day, and finally on 30th day for each individual. the test consists of a score of 1 to 10 that the patient gives to the sensitivity of the teeth in touch, cold and hot stimulants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age range 20-50 years, patients undergoing scaling treatment, presence of at least 3 sensitive teeth, exclusion criteria: allergy to the contents of toothpaste, generalized pathology in oral cavity, sensitive teeth with mobility higher than grade1, sensitive teeth suspected to pulpitis, enamel crack or caries, people taking anti epileptic, antihistamine, antidepressant, pregnant and lactating women

Intervention groups

Intervention group 1: Meridant toothpaste recipients to reduce tooth sensitivity following scaling and root planning (SRP) Intervention group 2: Pronamel toothpaste recipients to reduce tooth sensitivity following SRP

Main outcome variables

The amount of pain relative to cold, heat and touch stimuli,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100412003690N12**

Registration date: **2020-08-26, 1399/06/05**

Registration timing: **retrospective**

Last update: **2020-08-26, 1399/06/05**

Update count: **0**

Registration date

2020-08-26, 1399/06/05

Registrant information

Name

Masoomeh Faramarzie

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-10, 1399/05/20

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	patient and the evaluator of tooth hypersensitivity will not be aware of the type of toothpaste.
Scientific title Comparative evaluation of effectiveness of two toothpastes containing potassium nitrate in the treatment of dentinal hypersensitivity secondary to scaling and root planing	Placebo Not used
	Assignment Parallel
Public title Comparison of the effect of two different toothpastes in the treatment of dental hypersensitivity secondary to scaling	Other design features
Purpose Treatment	Secondary Ids empty
Inclusion/Exclusion criteria Inclusion criteria: The patient underwent scaling and Root Planning The presence of at least 3 teeth with dental hypersensitivity Exclusion criteria: History of allergy to toothpaste Compounds extensive pathology in the oral cavity Chronic systemic disease Teeth with tooth sensitivity with more than first degree mobility, teeth with extensive restoration or defect or with prosthetic coating, teeth suspected of pulpitis or with enamel cracking or caries Pregnant and lactating women Participants in the study were treated similarly to those who received any dental anti-sensitivity products last month	Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Tabriz University of Medical Sciences Street address International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz City Tabriz Province East Azarbaijan Postal code 5166614711 Approval date 2020-07-26, 1399/05/05 Ethics committee reference number IR.TBZMED.REC.1399.441
Age From 20 years old to 50 years old	
Gender Both	
Phase 3	
Groups that have been masked • Participant • Investigator • Outcome assessor	
Sample size Target sample size: 22	
Randomization (investigator's opinion) Randomized	
Randomization description Allocation of toothpaste to patients will be done randomly in such a way that the third person will pre-codify the toothpaste and distribute it in the same size plastic containers with code A or B and without any other markings. The type of toothpaste will be specified with the codes A (Iranian) and B (foreign) and placed inside the sealed envelopes, then the envelopes will be placed in a bag and shaken. Then it is randomly taken out of the bag and after observing the toothpaste code, it will be given to the patient. None of the patients are informed about the other patient's toothpaste	Health conditions studied 1 Description of health condition studied Dental Hypersensitivity ICD-10 code ICD-10 code description
Blinding (investigator's opinion) Double blinded	Primary outcomes 1 Description The intensity of pain in response to cold, heat and touch stimulants Timepoint In the first visit, 15 days later and finally on the 30th day Method of measurement Using Visual Analogue Scale
Blinding description The toothpaste will be placed by an third person in unmarked plastic containers and will be marked with codes A and B for each type of toothpaste. The allocation of toothpaste to patients will be by a third person so the	Secondary outcomes empty

Intervention groups

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Description

Intervention group 1: those who receive Merident desensitizing toothpaste, product of Pakshu company, which contains potassium nitrate; the toothpaste will be applied topically. to do this, the sensitive teeth will be covered for 2 minutes; at least 2 times a day for 1 month with the toothpaste after placing it on the toothbrush.

Category

Treatment - Drugs

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Description

Intervention group 2: those who receive Pronamel desensitizing toothpaste, product of Sensodyne company, which contains potassium nitrate; the toothpaste will be applied topically. to do this, the sensitive teeth will be covered for 2 minutes; at least 2 times a day for 1 month with the toothpaste after placing it on the toothbrush.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN

Full name of responsible person

Masoomeh Faramarzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Tabriz University of Medical Sciences

Full name of responsible person

Masoomeh Faramarzi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist