Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the Effectiveness of Nano Hydroxyapatite (n-HAP) with Potassium Nitrate (KNO3) in dental Hypersensitivity secondary to Periodontal Surgery in moderate to severe Periodontitis Patients

Protocol summary

Study aim

Comparison of the Effectiveness of Nano hydroxyapatite (n-HAP) with Potassium nitrate (KNO3) in Dental Hypersensitivity secondary to Periodontal Surgery Treatment in moderated to severe Periodontitis Patients

Design

Clinical trials, with Parallel Groups, Double-blinded and Randomized. Sampling Method is randomly available among Individuals referring to Periodontics Department of Tabriz Dental Faculty. The randomization Method is simple and the Unit is individual, our Tool for randomization is randomized Number Chart. Also, the Allocation of Toothpaste to Patients is done randomly. In this Way, the type of Toothpaste is identified with Code A (Sensodyne) and B (Pharmed) and sealed in Envelopes; then the Envelopes are placed in a Box and stirred Then they are randomly chosen from the Box and after observing the Code, the Toothpaste will be given to the Patient. None of the Patients will be informed about Another Patient's Toothpaste. Operator who evaluating dental Hypersensitivity is not informed about Type of Toothpaste. based on statistical Analysis Sample Size will be contained 22 Persons. Afterward They are divided in 2 groups; Sensodyne Toothpaste Recipients and Pharmed. dental Hypersensitivity is evaluated at first Visit, 15 Days later and finally on 30th Day for each Individual. The Test consists a Ranking of 1 to 10 that the Patient shows to the Sensitivity of his/her Teeth against Touch, cold and hot Stimulants. The two Groups will be unified based on Age and Gender. The Sampling Method in this Study includes considering the Difference of 1 unit between Tooth Pain in response to Stimulants after using Pharmed and Sensodyne Toothpaste with a standard Deviation of 1.45 (and adding 10% to this Number), 1.6. Also considering $\alpha = 0.05$ and Power of 80%, 10 Samples will be selected in each Group; Finally 10% will be added to this Number and 11 People will be selected for each Group in order to increase the Validity of this Study and eliminating Mistakes caused by dropped out Individuals during Implementation of the Plan.

Settings and conduct

This Study is a clinical Trial that will be carried out in the Periodontics Department of Tabriz dental Faculty. According to the statistical Analysis the Sample Size will be 22 People. Then They are divided into two Groups: Those who received Sensodyne Toothpaste is contained Potassium Nitrate and Pharmed Toothpaste is contained Nano Hydroxyapatite. The two Groups will be assimilated based on Age and Gender. Dental Hypersensitivity is determined at the Beginning of the Period, then on the fifteenth 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. it is a double-blind Fashion Study. None of the Participant does not know which Toothpaste another Participant will receive. Also Participants are not informed about Types of Toothpaste and the other Participants. The Operator evaluating dental Hypersensitivity will be blinded too.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age Range 15 to 60 Years Dental Hypersensitivity should be confirmed by an experienced Clinician Gingival Retraction secondary to Periodontal Surgery should be existed in Participant's Dentition Presence of At least Three sensitive Teeth Periodontal Diseases have been treated by Periodontal Surgery Exclusion criteria: Allergy to the Contents of Toothpaste Generalized Pathology in Oral Cavity Systemic chronic Disease Sensitive Teeth with Mobility Higher than Grade 1 Sensitive Teeth with Extent Restoration, Defect or Prosthetic Crown Sensitive Teeth suspected to Pulpitis, enamel Crack, Caries Abutment Teeth of removable Partial Denture People taking Anti epileptic, Antihistamine, Antidepressant, Antiinflamatory, Sedative Drugs or Analgesics Pregnant and Lactating Women Participants in similar Studies or People who have

received any kind of Desensitizing Products

Intervention groups

Group No.1: Participants who use Desensitizing Sensodyne Toothpaste which contains Potassium Nitrate for relieving dental Hypersensitivity following Periodontal Surgery. Group No2: Desensitizing Pharmed Toothpaste Recipients containing Nano Hydroxyapatite to reduce Postoperative dental Hypersensitivity following Periodontal Surgery.

Main outcome variables

The amount of Pain in response to cold, hot and Touch Stimulants at first Visit and then after 15 Days and 30 Days later; by Using Visual Analogue Scale Type of desensitizing Material in Toothpaste, containing Nano Hydroxyapatite in Pharmed Toothpaste and Potassium Nitrate in Sensodyne Toothpaste Time of Pain Evaluation for Participants in 3 Steps: first Visit, 15 Days later and 30 Days later

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100412003690N8**
Registration date: **2018-03-05, 1396/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-05, 1396/12/14**
Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Masoomeh Faramarzie

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-04-14, 1397/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Nano Hydroxyapatite (n-HAP) with Potassium Nitrate (KNO3) in dental Hypersensitivity secondary to Periodontal Surgery in moderate to severe Periodontitis Patients

Public title

Comparison of the Effectiveness of the desensitizing Toothpastes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of the dental Hypersensitivity by an experienced Clinician Gingival Retraction secondary to the periodontal Surgery Presence of at least Three sensitive Teeth Periodontal Conditions treated by periodontal Surgery

Exclusion criteria:

Allergy to the Contents of the Toothpaste Generalized Pathology in Oral Cavity Systemic chronic Disease Sensitive Teeth with Mobility higher than Grade 1 Sensitive Teeth with extent Restoration, Defect or prosthetic Crown Sensitive Teeth suspected to Pulpitis, enamel Crack, Caries Abutment Teeth of removeable partial Denture People taking Antiepileptic, Antihistamine, Antidepressant, Antiinflamatory, Sedative Drugs or Analgesics Pregnant and lactating Women People who have Participated in similar Studies or have received any kind of Desensitizing Products in three months

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling Method is randomly Available among Individuals referring to Periodontics Department of Tabriz Dental faculty. The randomization Method is simple and the Unit is individual, our Tool for randomization is the randomized Number Chart. Furthermore, the Allocation of Toothpastes to Patients is done Randomly. To do this, the types of the Toothpastes are identified with code A (Sensodyne) and B (Pharmed) and then the toothpastes are sealed in Envelopes that will be placed in a Box and stirred. Then they are randomly chosen from the Box and after observing the code, the Toothpaste is given to the Patient. None of the Patients will be informed about another Patient's Toothpaste. Operator who evaluating dental Hypersensitivity is not informed about Type of Toothpaste.

Blinding (investigator's opinion)

Double blinded

Blinding description

Present Study is conducted in double-blinded fashion. Participants do not know that different types of Toothpastes are being studied. They are also totally blinded to the information of the other Participants. The Operator evaluating the dental Hypersensitivity will also be blinded to the types of the toothpastes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Floor3, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

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Tabriz

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East Azarbaijan

Postal code
5166614711

Approval date
2018-02-26, 1396/12/07

Ethics committee reference number
IR.TBZMED.REC.1396.1082

Health conditions studied

1

Description of health condition studied
Dental Hypersensitivity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The Intensity of Pain in response to cold, hot and touch Stimulants

Timepoint
In the first Visit, 15 Days later and finally on the 30th Day

Method of measurement
Using Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Those who receive Sensodyne Desensitizing Toothpaste, 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

2

Description
Intervention Group 2: Those who receive Pharmed Desensitizing Toothpaste, 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
Tabriz University of Medical Sciences Dentistry Faculty Periodontics Department

Full name of responsible person
Dr Masoome Faramarzi

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Floor3, central building No.2, Tabriz University of Medical Sciences, Golgasht St.

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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
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
Periodontal and Dental Research Center
Full name of responsible person
Dr Masoome Faramarzi
Position
Professor of Periodontics
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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