

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of Sodium fluoride in the form of hydrogel in reducing root sensitivity after periodontal flap surgery

Protocol summary

Study aim

The effect of Sodium fluoride in the form of hydrogel in reducing root sensitivity after periodontal flap surgery

Design

This randomized clinical trial is a double-blinded study with a parallel design. This double-blinded study, randomized study, phases 2-3, will be conducted on 36 patients. A table of random numbers is used for randomization, and the participants are assigned to three intervention groups.

Settings and conduct

In this double-blind study, which will be conducted in the specialized periodontology department of Azad University of Isfahan, Khorasgan branch, the clinical caregiver and the patient are unaware of who will receive the new drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Systemically healthy patients with severe chronic generalized periodontitis with probing depth ≥ 5 mm; Radiographic evidence includes supraosseous horizontal bone loss
Exclusion criteria: Patients currently undergoing DH treatment; Patients with chronic systemic diseases and nerves; pregnant women; breastfeeding mothers

Intervention groups

In the first intervention group, a small brush is dipped in sodium fluoride solution and used on the buccal surfaces of the root, then sutured. In the second intervention group, 3 cc of hydrogel form in the form of pluronic acid f127 to provide mechanical properties and easy exit from the syringe at 37 degrees, and Kropel p 934 to create a hydrogen bond with the tooth and sodium fluoride were used before suturing. In the third intervention group, before suturing, a small brush is immersed in normal saline solution and used on the buccal surfaces of the roots.

Main outcome variables

Sensitivity to touch test, sensitivity to heat, sensitivity to cold

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N190**

Registration date: **2022-12-09, 1401/09/18**

Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**

Update count: **0**

Registration date

2022-12-09, 1401/09/18

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Sodium fluoride in the form of hydrogel in reducing root sensitivity after periodontal flap surgery

Public title

Comparison the effect of Sodium fluoride in reducing root sensitivity after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Systemically healthy patients with severe chronic generalized periodontitis with probing depth ≥ 5 mm Radiographic evidence includes supraosseous horizontal bone loss

Exclusion criteria:

Patients currently undergoing DH treatment Patients with chronic systemic diseases and nerves pregnant women Patients with eating disorders and digestive disorders History of tooth cracking, root canal treatment, chipped teeth, abrasion, faulty restorations, orthodontic devices, fixed prosthesis, artificial teeth Deep caries lesions and periodontal surgery in the last 6 months Patients with less than 6 teeth

Age

From **40 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple random method. Numbers 1 to 36 are written on 36 cards. The 12 numbers that are randomly selected in the first stage are assigned to the first group. The 12 numbers that are randomly selected in the second stage are assigned to the second group, and the 12 numbers that are randomly selected in the third stage are assigned to the third group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are informed about participating in the study and receiving the new drug, but the clinical caregiver and the participant will be kept blind to what type of drug each group will receive. Medicines can only be identified through the serial number on the container. The serials are with the main researcher and will remain confidential until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Khorasgan branch

Street address

Vice Chancellor for Research Affairs, University Blvd., Arghwanieh, J Sharghi Street

City

Isfahan

Province

Isfahan

Postal code

8155139998

Approval date

2022-11-06, 1401/08/15

Ethics committee reference number

IR.IAU.KHUISF.REC.1401.239

Health conditions studied

1

Description of health condition studied

Flap surgery

ICD-10 code

K05.5

ICD-10 code description

Other periodontal diseases

Primary outcomes

1

Description

Sensitivity to touch test

Timepoint

1st, 2nd, 4th and 6th week after periodontal surgery

Method of measurement

Using a sharp probe

2

Description

Sensitivity to heat test

Timepoint

1st, 2nd, 4th and 6th week after periodontal surgery

Method of measurement

Using gutta-percha

3

Description

Sensitivity to cold

Timepoint

1st, 2nd, 4th and 6th week after periodontal surgery

Method of measurement

Using cold spray

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, a small brush is dipped in sodium fluoride solution and used on the buccal surfaces of the root, then sutured.

Category

Treatment - Other

2

Description

In the second intervention group, 3 cc of hydrogel form in the form of pluronic acid f127 to provide mechanical properties and easy exit from the syringe at 37 degrees, and Kropel p 934 to create a hydrogen bond with the tooth and sodium fluoride were used before suturing

Category

Treatment - Other

3

Description

. In the third intervention group, before suturing, a small brush is immersed in normal saline solution and used on the buccal surfaces of the roots.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Azad University Dental Faculty

Full name of responsible person

Vahedeh Sharifi

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Faculty of Dentistry, University Blvd., Arghwanieh, J Sharghi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Majid Meshkini

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Vahedeh Sharifi

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available