

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment Of Propolis, Dentin Bonding Agent And Placebo In Reducing Dentinal Hypersensitivity, In Hypersensitive Teeth Subsequent Of Periodontal Surgeries: A Randomized Clinical Trial

Protocol summary

Summary

Objectives: This randomized clinical trial study was aimed to evaluate the effect of two desensitizing agents on reduction of Dentin Hypersensitivity (DH) subsequent of periodontal surgeries. **Design:** A sample of 120 teeth from 96 patients, among which maximum 2 teeth had DH, was randomly allocated into 4 treatment groups: Group 1 treated with 10% ethanolic extract of Propolis, Group 2 treated with 30% ethanolic extract of Propolis, Group 3 treated with dentin bonding agent and Group 4 with Distilled water (placebo). In patients with one hypersensitive tooth, Randomization was performed for the first 12 patients with 12 opaque envelopes that containing 3 cards stipulating 'Dentin bonding agent', 3 cards 'Propolis 10%', 3 cards 'Propolis 30%' and 3 envelopes containing 3 cards stipulating 'Distilled water' (block randomization). After the first 12 patients, the randomization process was repeated until 4 groups were completed. But, patients with two hypersensitive teeth, were randomized by 4 opaque envelopes that containing 1 card stipulating 'Dentin bonding agent', 1 card 'Propolis 10%', 1 card 'Propolis 30%' and 1 envelope containing 1 card stipulating 'Distilled water'. **Setting and conduct:** Visual Analogue Scale (VAS) was used to record the degree of hypersensitivity, based on patients' response to tactile and air blast stimuli. Pain response was evaluated before treatment and at 1, 7, 14, 21, 60 and 90-day intervals. **Participants:** Patients who had periodontal surgery in Department of Periodontology in Dentistry Collegial of Tehran University; With maximum 2 not adjacent caries-free teeth with dentinal hypersensitivity at the cervical border. **Exclusion Criteria:** Teeth with dental caries, cracks or fractures in the cervical borders of the teeth; Teeth with any extensive and incorrect restorations, being of prostheses or orthodontic appliances; Patients with a history of use of any desensitizing agents. **Intervention:** In group which

treated with dentin bonding agent, light cure LED with 400-550 mW/cm² power used for 15 seconds. Also application of placebo (distilled water) recommended 2 times a day for 4 weeks. In groups 10% and 30% Propolis and Distilled water, placebo exposure was used after first application. So patients applied gel or distilled water in each group, 2 times a day for 4 weeks. **variables:** Degree of pain

General information

Acronym

D.DH

IRCT registration information

IRCT registration number: **IRCT2016102430475N1**

Registration date: **2016-11-18, 1395/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-18, 1395/08/28

Registrant information

Name

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Name of organization / entity

Tehran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Faculty of Dentistry, Tehran University Of Medical

Expected recruitment start date

2016-01-07, 1394/10/17

Expected recruitment end date

2016-03-18, 1394/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment Of Propolis, Dentin Bonding Agent And Placebo In Reducing Dentinal Hypersensitivity, In Hypersensitive Teeth Subsequent Of Periodontal Surgeries: A Randomized Clinical Trial

Public title

Comparision of Two Dentinal Desensitizing Agents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients who had periodontal surgery in Department of Periodontology in Dentistry Collegial of Tehran University; Patients who had maximum 2 not adjacent caries-free teeth with dentinal hypersensitivity at the cervical border; Patients with adequate and good oral hygiene; Patients with complete general and physical health . Exclusion Criteria: Patients who has any systemic illnesses and/or psychological diseases, and previous hospitalization; Teeth with dental caries, cracks or fractures in the cervical borders of the teeth; Teeth with any extensive and incorrect restorations,being of prostheses or orthodontic appliances; Patients who were drug addicted and analgesic and/or anti-inflammatory drugs users; Patients with a history of use of any desensitizing agents.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science

City

Tehran

Postal code

Approval date

2016-01-05, 1394/10/15

Ethics committee reference number

IR.TUMS.REC.1394.1567

Health conditions studied

1

Description of health condition studied

Dentinal Hypersensitivity

ICD-10 code

k03.8

ICD-10 code description

Other specified diseases of hard tissues of teeth

Primary outcomes

1

Description

Dentinal Hypersensitivity

Timepoint

1,7,14,21,60 and 90-day

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

In group which treated with 'Dentin Bonding Agent', light cure LED with 400-550 mW/cm² power used for 15 seconds. Also application of placebo(distilled water) recommended after drying and isolation of teeth by using disposable micro brush 2 times a day for 4 weeks. Treatment Evaluation Procedure: Each tooth received two stimuli: Air Blast and Tactile. The degree of hypersensitivity was reported by Visual Analogue Scale(VAS), from 0 to 10, The values were collected

before the intervention(baseline values) and after each applications, on days 1,7,14,21,60 and 90 respectively.

Category
Treatment - Other

2

Description

In group which treated with '10% Propolis', placebo exposure was used after first application. So patients applied gel after drying and isolation of teeth by using disposable micro brush 2 times a day for 4 weeks. Treatment Evaluation Procedure: Each tooth received two stimuli: Air Blast and Tactile. The degree of hypersensitivity was reported by Visual Analogue Scale(VAS) in before the intervention(baseline values) and after each applications, on days 1,7,14,21,60 and 90 respectively.

Category
Treatment - Drugs

3

Description

In group which treated with '30% Propolis', placebo exposure was used after first application. So patients applied gel after drying and isolation of teeth by using disposable micro brush 2 times a day for 4 weeks. Treatment Evaluation Procedure: Each tooth received two stimuli: Air Blast and Tactile. The degree of hypersensitivity was reported by Visual Analogue Scale(VAS) in before the intervention(baseline values) and after each applications, on days 1,7,14,21,60 and 90 respectively.

Category
Treatment - Drugs

4

Description

In group which treated with 'Distilled Wather', placebo exposure was used after first application. So patients applied Distilled Wather after drying and isolation of teeth by using disposable micro brush 2 times a day for 4 weeks. Treatment Evaluation Procedure: Each tooth received two stimuli: Air Blast and Tactile. The degree of hypersensitivity was reported by Visual Analogue Scale(VAS) in before the intervention(baseline values) and after each applications, on days 1,7,14,21,60 and 90 respectively.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Department Of Periodontology,Dentistry
Faculty,Tehran University Of Medical Sciences

Full name of responsible person
Melia Zargar

Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dentistry faculty,Tehran university of medical sciences

Full name of responsible person
Mitra Montazer

Street address
Dentistry Faculty Pardis, Mahan Street, Navab Highway

City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dentistry faculty,Tehran university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Dentistry faculty, Tehran University Of Medical Sciences

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Student Of Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Dentistry Faculty, Tehran University Of Medical Sciences

Full name of responsible person