Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative evaluation of the effects of CPP-ACPF paste and propolis tooth paste on treatment of dentinal hypersensitivity.

Protocol summary

Study aim
Comparison of the effect of toothpaste containing CPP_ACPF and toothpaste containing propolis in the treatment of dentin hypersensitivity

Design
Randomized clinical trial without control group, parallel groups trial with blinded statistical analyzer; phase 2 on 20 patients.

Settings and conduct
This study will be done on patients with dentin hypersensitivity referring department of periodontics of Isfahan University. Two propolis Herbex and GC MI PASTE PLUS pastes are tested. Statistical analyzer is blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to the general and specialized periodontics department of Isfahan Dental School; Teeth do not need restorative treatment; People over 18 years old. Non-inclusion criteria: erosion, abrasion, attrition, crack , pulp inflammation, chronic disease and periodontal disease; active caries, restored teeth, coronary fractures; Pregnancy and lactation; smoking; use anti-sensitive toothpaste during the last 6 weeks; sensitivity to milk protein and Benzoate

Intervention groups
Intervention group 1:CPP_ACPF Use of GC MI PASTE PLUS once a day for two months. Intervention group 2: Propolis Use of PROPOLIS HERBEX toothpaste with a soft toothbrush twice a day for two months.

Main outcome variables
Dentin sensitivity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120901010703N4**
Registration date: **2020-11-17, 1399/08/27**
Registration timing: **prospective**
Last update: **2020-11-17, 1399/08/27**
Update count: **0**

Registration date
2020-11-17, 1399/08/27

Registrant information

Name
Narges Naghsh

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 1792 5564

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-04-21, 1400/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of the effects of CPP-ACPF paste and propolis tooth paste on treatment of dentinal hypersensitivity.

Public title
Comparison of the effect of CPP-ACPF and propolis in the treatment of dentin sensitivity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients referred to the general and specialized periodontics department of Isfahan Dental School have at least 2 teeth with complaints of cervical dentin sensitivity and sensitivity to cold stimuli that are not adjacent to each other Patients should be available for three months during the study period and sign the informed consent form Teeth do not need restorative treatment People over 18 years old

Exclusion criteria:

Erosion, abrasion, attrition, crack and pulpitis, chronic disease and periodontal disease Existence of active caries, restored teeth, coronary fractures Candidate teeth receiving veneers, teeth with ortho braces People who have received antihistamines, antidepressants, and sedatives in the month before or during the study. Pregnant and lactating people smoking Patients who have used anti-sensitive toothpaste for the past 6 weeks. Milk protein sensitivity Sensitivity to benzoate Improper diet (use of sour and acidic foods)

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

2 teeth

Randomization (investigator's opinion)

Randomized

Randomization description

According to the number of available pastes, there are papers with the paste name written on them and placed in a box. Each sample person picks a paper from the box and receives the desired paste.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer does not know the type of paste used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology; Building No. 4; Isfahan University of Medical Sciences and Health Services; Hezar Jerib St.,

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Postal code

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Approval date

2020-09-23, 1399/07/02

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.421

Health conditions studied

1

Description of health condition studied

Dentin hypersensitivity

ICD-10 code

K03.89

ICD-10 code description

Other specified diseases of hard tissues of teeth

Primary outcomes

1

Description

Amount of patient's pain (dentin hypersensitivity)

Timepoint

Before treatment, 15 minutes after treatment in the first session, one week after the first session, two weeks after the first session, one month after the first session, two months after the first session

Method of measurement

Use of cold spray, use of air syringe of unit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Herbex toothpaste, contains propolis. Brush teeth twice a day for two months. It is produced by Dr. Jahangir Knowledge-Based Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Intervention group 2: GC MI Paste Plus. Contains CPP_ACPF. Once a day for two months, after brushing, at least one pea size for each jaw is placed on the surface of the teeth with the help of a clean, dry finger. It is produced by GC AMERICA INC

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, School of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person

Elham Amini

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Department of Periodontics; Dentistry School; Isfahan University of Medical Sciences and Health Services; Hezarjrib street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Narges Naghsh

Position

Assistant 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