

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Toothpaste containing Propolis on Dental Plaque on Dentistry Students of Zahedan, Dental School

Protocol summary

Study aim

In this study, we examine the effect of propolis on plaque accumulation and gingivitis.

Design

30 dentistry students participate in this study. At first, all students undergo gingival examinations; and for each of them, in the base line, the gingival and plaque indices are prepared and the teeth plaque is removed using piezoelectric and then the teeth are disinfected with anaglyc, robercup and prophylaxis paste, so that the mouths of the subjects are completely free from microbes and plaster plates. Three types of toothpaste are available, one of which is with Propolis and the other without Propolis and the third type is the seven-purpose Crest toothpaste, which is made in Germany. Products available in two toothpaste initially mentioned include calcium carbonate, sorbitol, sodium sulfate Laryl, Mint, sodium saccharin, titanium oxide. Both toothpaste contains all of the above ingredients. The only difference between the effective toothpaste and the control toothpaste is the presence of Propolis biologic composition in the toothpaste, which is considered as a specific percentage (1%), making it standardized by the Kerman Pharmaceutical Group. The students are divided into two groups, the first one is given toothpaste containing propolis and soft toothbrush, and the second group is given propolis-free toothpaste and soft brush and they are asked to brush through the Bass technique according to the teachings. After 2 weeks of using toothpastes, gum and plaque indexes are available for all subjects. After a week's Wash out, in which students use common oral and toothpaste procedures that they provide, all students undergo gingival examinations, and gum and plaque indicators are provided for each person, and if needed the teeth were polished and root leveling is done in order to the Terms of using the both types of toothpaste be the same after the first toothpaste without propolis and the second group toothpaste containing propolis appears and again after 2 weeks of use to

anyone indices gingival And plaque. Then, the first group is given toothpaste without propolis and the second group is given toothpaste containing propolis, and again after 2 weeks of use, gum and plaque indexes are prepared for all people.

Settings and conduct

All gingival examinations are performed by a dentistry student who has received enough training for this work, under the supervision of an expert in gum surgery (faculty member of the university). The standard tester is calibrated before the beginning of the study. At first, a 10-member group is selected, and for two consecutive days, the plaque index and Gingival index are measured, then the reliability of the tester is measured by Kappa analysis. Toothpastes replicated by someone else are given to patients and thus the patient and the therapist are unaware of the type of toothpaste used (Double blind).

Participants/Inclusion and exclusion criteria

Entry requirements: Dental students aged 18 to 25 who participated on a voluntary basis. Conditions for not admitting: People who are allergic to the substances used in the study; ; People with periodontal disease; People with immune diseases like diabetes, AIDS, hepatitis and so on.

Intervention groups

The students are divided into two groups, the first one is given toothpaste containing propolis, and the second group is given propolis-free toothpaste

Main outcome variables

Due to the properties of propolis, it is expected that propolis toothpaste will reduce gingival plaque and gingivitis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180122038475N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

somaye ansarimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3344 1814

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-05-15, 1397/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Toothpaste containing Propolis on Dental Plaque on Dentistry Students of Zahedan, Dental School

Public title

The Effect of Toothpaste containing Propolis on Dental Plaque

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Dental students aged 18-25 years who volunteered to participate

Exclusion criteria:

Those having a history of hypersensitivity to any product used in the present study Those having periodontal disease Subjects suffering from immune compromised states such as diabetes, AIDS, hepatitis, etc

Age

From **18 years** old to **25 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random block method, subjects will be categorized in one of the two examined groups. Randomly, numbers from one form of 1 to 10 are selected and written in sequence. We assign the numbers below 5 as AB and assign the upper 5 numbers to BA and based on the given number we categorize persons in either AB or BA group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The same toothpastes are provided by the other person to the patients and so the patient, the therapist, and the researcher are unaware of the type of toothpaste used, and also the person who is analyzing the data is unaware of the kind of used toothpaste.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Doctor Hesabi Sq. Zahedan, Iran

City

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Province

Sistan-va-Balouchestan

Postal code

9817699693

Approval date

2018-01-14, 1396/10/24

Ethics committee reference number

IR. ZAUMS. REC.1396.331

Health conditions studied

1

Description of health condition studied

Gingivitis and periodontal diseases

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

plaque index

Timepoint

1 to 14 days after start

Method of measurement

Sillness and Loe index

2

Description

gingival index

Timepoint

Sillness and Loe

Method of measurement

Sillness and Loe index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use of Toothpaste containing Propolis. Products available in toothpaste include calcium carbonate, sorbitol, sodium sulfate Laryl, Mint, sodium saccharin, titanium oxide and propolis(1%), making it standardized by the Kerman Pharmaceutical Group

Category

Prevention

2

Description

Control group: Use of Toothpaste without Propolis: . Products available in toothpaste include calcium carbonate, sorbitol, sodium sulfate Laryl, Mint, sodium saccharin, titanium oxide, making it standardized by the Kerman Pharmaceutical Group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Periodontics Dentistry Department, Dental College of Zahedan

Full name of responsible person

Somaye Ansari Moghadam

Street address

Dental College of Zahedan University of Medical Sciences, Azadegan St. Zahedan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nour Mohammad Bakhshani

Street address

Ethics Committee of Zahedan University of Medical Sciences

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Somaye Ansari Moghadam

Position

Assistant Professor of Periodontics Department,
Dental College of Zahedan University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Somaye Ansari Moghadam

Position

Assistant Professor of Periodontics Department,
Dental College of Zahedan University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Full name of responsible person

Alireza Raeisi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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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