Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 dissected 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
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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
Zahedan
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
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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
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Full name of responsible person
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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

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Name of organization / entity
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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