

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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 disected 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)

**Phone**

+98 54 3344 1814

**Email address**

ansarimoghadam@zaums.ac.ir

**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

##### Street address

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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9817699693

##### Phone

+98 54 3341 4004

##### Email

Ansarimoghadam@zaums.ac.ir

## 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9817699693

##### Phone

+98 54 3329 5715

##### Email

ansarimoghadam@zaums.ac.ir

#### 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

**Street address**

یران، زاهدان، خیابان آزادگان، دانشکده دندان پزشکی دانشگاه  
علوم پزشکی زاهدان

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3344 1824

**Email**

ansarimoghadam@zaums.ac.ir

## 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

**Street address**

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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3344 1824

**Email**

Ansarimoghadam@zaums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Alireza Raeisi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9817699693

**Phone**

+98 54 3344 1824

**Email**

dr.alireza91@yahoo.com

## 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