

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluation of Propolis Gel Under the Periodontal Dressing (Coe-Pack® GC America INC) on Gingival Healing Index After Periodontal Flap Surgery

#### Protocol summary

##### Study aim

The aim of the present study was to evaluate the effectiveness of Propolis gel under Coe-Pack on gingival on Gingival Healing Indices after periodontal flap surgery.

##### Design

Clinical trials have a control group, two-way blind, easily randomized, phase 3 on 18 patients. The flip coin method was used to randomize each side of the mouth

##### Settings and conduct

In the specialized department of the Faculty of Dentistry, University of Isfahan. Selection of 20 patients by easy sampling method. Everyone is blind except the clinical caregiver. Select the patient's first position using the flip coin method and place in group A. also, gel and placebo have A and B labels

##### Participants/Inclusion and exclusion criteria

Entry requirements: Patients with moderate to severe chronic Periodontitis require two side or whole mouth periodontal flap surgery that is systemically healthy The same type of flap on both sides in each person Age over 18 years Pelaque index Less than or equal to 1 after health education No contraindications for surgery No need for prophylactic Antibiotics Do not take Corticosteroids or Hormones for the past two months Having acceptable cooperation Conditions of non-entry: Smoking Pregnancy Taking anti-inflammatory drugs or Antibiotics Existence of systemic disease Pelaque index 2 or 3 after health education Need to cut more than 2 mm of bone Lack of cooperation and patient satisfaction

##### Intervention groups

Treatment group: after surgery, use 20% propolis gel, which is made by Propolis Manufacturing Company (Green Plants of Life Company) under the Coe Pack dressing(GC America Inc), and then mix the Coe Pack thoroughly and apply it on the surgery site Control group: after periodontal flap surgery, we place the placebo gel and then put the Coe Pack dressing( GC America inc) on the desired place

##### Main outcome variables

Pain index, plaque index, papillary bleeding index, healing index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150210021029N2**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

##### Registration date

2020-05-17, 1399/02/28

##### Registrant information

##### Name

Sima Kiani

##### Name of organization / entity

Department of Periodontology, dental school, Isfahan university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 2842

##### Email address

simakiani@dnt.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-26, 1399/03/06

##### Expected recruitment end date

2020-09-27, 1399/07/06

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of Propolis Gel Under the Periodontal Dressing (Coe-Pack® GC America INC) on Gingival Healing Index After Periodontal Flap Surgery

**Public title**  
Effect of Propolis Gel under Dressing of periodontal flap surgery

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with moderate to severe chronic Periodontitis require two side or whole mouth periodontal flap surgery that is systemically healthy The same type of flap on both sides in each person Age over 18 years Pellaque index  $\leq 1$  after health education No contraindications for surgery No need to cut more than 2 mm of bone No need for prophylactic Antibiotics Do not take Corticosteroids or Hormones for the past two months Having acceptable cooperation  
**Exclusion criteria:**  
Smoking Pregnancy Taking anti-inflammatory drugs or Antibiotics Existence of systemic disease Pellaque index 2 or 3 after health education Need to cut more than 2 mm of bone Lack of cooperation and patient satisfaction

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **20**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
Each person has one side of the mouth as a Control and the other side as an example of treatment

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Participants in the study were selected by Simple Randomization method, individually and with Random number table tools. The intervention was performed as Split-Mouth, and the choice of Quadrant for Intervention or Control was randomly performed with Coin instruments.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

Participant: In this study, due to the presence of surgical Drapes, it is not possible to detect the direction in which the Propolis and Placebo are located Data Analyzer: Data is evaluated as a number without specifying the position of the Propolis and the Placebo Researcher and evaluator: The first side of each person is selected by the flip coin method and put in group A, which is aware of the clinical caregiver, and the other side is in group B. gel and placebo have A and B labels

**Placebo**  
Used

**Assignment**  
Single

**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

Isfahan university of medical sciences, Hezarjerib Ave, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

7346181746

#### Approval date

2020-02-25, 1398/12/06

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.699

## Health conditions studied

### 1

#### Description of health condition studied

Periodontal flap surgery

#### ICD-10 code

K05.6

#### ICD-10 code description

Periodontal disease, unspecified

## Primary outcomes

### 1

#### Description

Gingival healing index

#### Timepoint

One week after surgery, Two weeks after surgery, One month after surgery

#### Method of measurement

The healing rate is assessed based on tissue color, probe bleeding, granular tissue, cut margin, and discharge with five excellent, very good, good, weak, and very weak words

## Secondary outcomes

### 1

#### Description

Pelae index

#### Timepoint

Before surgery, One week after surgery, Two weeks after surgery and One month after surgery

#### Method of measurement

Based on the Silness and Loe method, it is evaluated in which the absence of Plaque(grade 0) to very large Plaque(grade 3) is ranked

### 2

#### Description

Papillary bleeding index

#### Timepoint

Before surgery, One week after surgery, Two weeks after surgery and One month after surgery

#### Method of measurement

It shows the rate of papillary bleeding by probe in 4 ranks, from non-bleeding (grade 0) to spontaneous bleeding (grade 3)

### 3

#### Description

Pain index

#### Timepoint

Before surgery, One week after surgery, Two weeks after surgery and One month after surgery

#### Method of measurement

By the Visual Analog Scale form

## Intervention groups

### 1

#### Description

Intervention group: After the surgery, we use the 20% Propolis gel, which is made by the Company that produces the Propolis (Green Plants of Life Company) under the Coe Pack( GC America inc), and then we mix the Coe Pack completely and place it on the surgical site.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: After the periodontal flap surgery, we put the Placebo gel and then put the Coe Pack( GC America inc) dressing on the desired place

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan University of Medical Sciences, School of Dentistry

##### Full name of responsible person

Sima Kiani

##### Street address

School of Dentistry, Isfahan university of medical sciences, Hezarjerib Ave, Isfahan

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##### Phone

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##### Email

research@dnt.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Nakisa Torabinia

##### Street address

Research vice chancellor, Isfahan Dental School, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan

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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**  
Sima Kiani  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Position**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Document Title: Data related to Personal information and Indicators examined in the study. All Data can be shared after People have not been identified

### When the data will become available and for how long

Up to One year after publication of the Article

### To whom data/document is available

Researchers working in Academic and Scientific Institutions

### Under which criteria data/document could be used

In addition to mentioning the Name and Academic affiliation, the Applicant must have signed a letter stating that He or She does not intend to publish or use any of our study Data in Person

### From where data/document is obtainable

Applicants can contact this E-mail: skiani.dnt@gmail.com

### What processes are involved for a request to access data/document

The Project Manager will provide the requested Documents via E-mail no later than One week after receiving the E-mail from the Applicant

## Comments