

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 ≤ 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

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3669 2588

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

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3792 5512

Email

research@dnt.mui.ac.ir

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
Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan
City
Isfahan
Province
Isfahan
Postal code
7346181746
Phone
+98 31 3792 5542
Email
skiani.dnt@gmail.com

Person responsible for scientific 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
Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan
City
Isfahan
Province
Isfahan
Postal code
7346181746
Phone
+98 31 3792 5542
Email
skiani.dnt@gmail.com

Person responsible for updating data

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
Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezarjerib Ave, Isfahan
City
Isfahan
Province
Isfahan
Postal code
7346181746
Phone
+98 31 3792 5542
Email
Simakiani@dnt.mui.ac.ir

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