Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Periodentology, 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 Pelaque 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 Pelaque 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

Isfehan

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
Pelaque 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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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