Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of comparison the effect of the propolis extract in combination with dressing without eugenol (Coe-Packtm) and Coe Packtm dressing in wound healing among patients undergoing crown lengthening surgery

Protocol summary

Summary

Objective: Comparison of the effect of propolis extract in combination with coe-packtm dressing and coe-packtm dressing alone on wound healing after crown lengthening surgery. Design: It is a randomized double blind placebo control clinical trial. At the end of crown lengthening surgery, 36 patients were randomly divided into two groups intervention and control groups. Randomization was carried out using opaque envelopes. Inclusion criteria: The patients in whom bone removal scale in surgery was between 1-2 mm, their surgical time duration lasted between 90-115 minutes and had been used from chisels and bur in their surgery. Exclusion Criteria: Occurrence of pulp change in the operated tooth following surgery; losing a part or all of the periodontal dressing; smoking; being allergic to the dressing material. Intervention: The patients were divided in two randomized groups; trial group: propolis extract combination with coe-packtm and control group: coe-packtm alone as a periodontal dressing. In control group, the dressing was mixed according to the manufacturer's instruction. Dressing was put on the wound and was adjusted to make a suitable shape. Dressing in trial group was the same, but across every 5 mm of dressing paste, 0.1 mm of 20% propolis hydroalcoholic solution (soren Tech Toos, Mashhad, Iran) was added to form the final dressing composition and the composition was put on the wound. Outcomes of interest: Pain; Burning; Consistency of gingiva; colour compatibility; Infection

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016102630475N2**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Mitra Askari

Name of organization / entity

Tehran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5585 1131

Email address

m-askari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Dentistry Faculty,Tehran University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison the effect of the propolis extract in combination with dressing without eugenol (Coe-Packtm) and Coe Packtm dressing in wound healing among patients undergoing crown lengthening surgery

Public title
The effect of the propolis in oral wound healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: bone removal scale in their surgery was between 1-2 mm; their surgical time duration lasted between 90-115 minutes and had been used from both of chisels and bur in their surgery; don't have any systematically problem; no periodontal disease in the surgical site; no restriction on surgery; don't need to the antibiotic prophylaxis during the surgery; don't use the corticosteroids or hormone in the last 2 months.
Exclusion criteria: when there is a problem in recording the patient's information; smoking.
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Tehran University of Medical Science
Street address
Ghods St., Keshavarz Blvd
City
Tehran
Postal code
Approval date
2016-01-02, 1394/10/12
Ethics committee reference number
IR.TUMS.REC.1394.1943

Health conditions studied

1

Description of health condition studied
-
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Pain
Timepoint
0,1,2,3,4,5,6 and 7 days after surgery
Method of measurement
Visual Analog Scale

2

Description
Burning sensation
Timepoint
0, 1,2,3,4,5,6 and 7 days after surgery
Method of measurement
Visual Analog Scale

3

Description
Consistency of gingiva
Timepoint
7th day after surgery
Method of measurement
palpation with a blunt instrument

4

Description
colour compatibility
Timepoint
7th day after surgery
Method of measurement
Visual Analog Scale

5

Description
Infection
Timepoint
2nd & 7th days after surgery
Method of measurement
Clinical examination

6

Description
Bleeding during probing
Timepoint
7th day after surgery
Method of measurement
Probing

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Control group: The patients washed their mouth before surgery with chlorhexidine 0.12% for 30 seconds. Lidocaine 2% with epinephrine 1:100000 (Septodont, France) were prescribed for local anesthesia, too. After pulling over the flap and bringing out the granulation tissue, osteotomy with 13K/TG krikland periodontal chisel (Hu-Friedy Dental Instruments ,Chicago, USA), carbide burs (JOTA AG Rotary Instruments, Ruthi, Switzerland) under irrigation with saline solution until obtaining a distance of 3mm from bone crest to the most cervical portion of the cavity that was measured with a Williams periodontal probe (Neumar®). At the end of the procedure, a simple suture was performed with some silk thread (Supa, Iran). Time duration from the first cut to the last stitch for all the patients has been between 90–115 minutes. After surgery, the patients were divided into two randomized groups. In control group, the dressing was mixed with sterile spatula on a sterile glass plate according to the manufacturer's instruction. Dressing was formed on the wound to adjust moderately. All the patients were educated to control the plaque with chlorhexidine 0.12% every 12 hours during 7 days and Ibuprofen 400 mg was prescribed every 6 hours, if necessary. Number and time of beginning the paregoric was recorded, too. All the patients received written and oral postoperative instructions. Some objective and subjective criteria were used to study the healing process.
Category
Treatment - Drugs

2

Description
Intervention group: The patients washed their mouth before surgery with chlorhexidine 0.12% for 30 seconds. Lidocaine 2% with epinephrine 1:100000 (Septodont, France) were prescribed for local anesthesia, too. After pulling over the flap and bringing out the granulation tissue, osteotomy with 13K/TG krikland periodontal chisel (Hu-Friedy Dental Instruments ,Chicago, USA), carbide burs (JOTA AG Rotary Instruments, Ruthi, Switzerland) under irrigation with saline solution until obtaining a distance of 3mm from bone crest to the most cervical portion of the cavity that was measured with a Williams periodontal probe (Neumar®). At the end of the procedure, a simple suture was performed with some silk thread (Supa, Iran). Time duration from the first cut to the last stitch for all the patients has been between 90–115 minutes. After surgery, the patients were divided into two randomized groups. After surgery, the patients were divided in two randomized groups. In trial group propolis extract was combined with coe-packtm. Then the dressing was mixed with sterile spatula on a sterile glass plate according to the manufacturer's instruction. Dressing was formed on the wound to adjust moderately. Dressing in trial group was as the same as control group except adding 0.1 mm of 20% propolis hydroalcoholic solution (soren Tech Toos, Mashhad, Iran) per every 5 mm of dressing paste to the final dressing composition and placing that on the wound. This amount of propolis extract didn't have any impact on the final dressing formidability. All the patients were educated to control the plaque with chlorhexidine 0.12% every 12 hours during 7 days and Ibuprofen 400 mg was prescribed every 6 hours, if necessary. Number and time of beginning the paregoric was recorded, too. All the patients received the written and oral postoperative instructions. Some objective and subjective criteria was used for studying the healing process.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Periodentology ward, Pardis Dentistry Faculty Of Tehran University of Medical Sciences
Full name of responsible person
Atena Beiky
Street address
Mahan St., Navab Blvd
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Dentistry faculty, Tehran University Of Medical Sciences
Full name of responsible person
Mitra Montazer
Street address

Pardis Dentistry Faculty, Tehran University Of Medical Sciences, Mahan St, Ñavab Blvd,Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Dentistry faculty, Tehran University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dentistry faculty, Tehran University Of Medical Sciences

Full name of responsible person

Atena Beiky

Position

Student Of Dentistry

Other areas of specialty/work

Street address

Dentistry faculty Of Tehran University Of Medical Sciences, Mahan St., Navab Blv.

City

Tehran

Postal code

Phone

+98 21 5585 1131

Fax

Email

Atena. beiki69@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dentistry Faculty, Tehran University Of Medical Sciences

Full name of responsible person

Mitra Askari

Position

Assistant

Other areas of specialty/work

Street address

Department Of Pathology, Dentistry Faculty, Tehran University Of Medicine Sciences, North Amir Abad St.

City

Tehran

Postal code

Phone

+98 21 5585 1131

Fax

Email

Askari_mitra@ymail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Mitra Askari

Position

Assistant

Other areas of specialty/work

Street address

Department Of Pathology, Dentistry Faculty, Tehran University Of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 5585 1131

Fax

Email

Askari_mitra@ymail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty