Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of non-eugenol periodontal dressing (Coe-Pak) on pain and wound healing after crown lengthening surgery

Protocol summary

Study aim

Providing a clinical approach to reduce pain and accelerate wound healing following crown-lengthening surgery using Coe-Pak dressing, with the aim of improving the quality of postoperative care and increasing patient satisfaction.

Design

ترجمهٔ انگلیسی متن شما: This is a phase 3 randomized clinical trial with a control group, parallel groups, and single-blind design, conducted on 70 patients. The random allocation sequence will be generated using Random Allocation Software with a block size of two.

Settings and conduct

Patients presenting to Mashhad Dental School who require crown-lengthening surgery will be assigned to two groups: the intervention group (placement of Coe-Pak dressing) and the control group (no Coe-Pak dressing). In this study, pain will be assessed using a questionnaire completed by the patient and the dentist, based on the Visual Analog Scale (VAS) and the number of analgesics consumed, while healing will be evaluated using the Early Healing Index (EHI). Blinding: Single-blind (the study participants are blinded).

Participants/Inclusion and exclusion criteria

Lack of willingness to continue cooperation during the study Failure to attend postoperative follow-up visits Partial or complete loss of the periodontal dressing Age 18 years and older Ability to respond to the questionnaire items Absence of systemic disease Need for functional crown-lengthening surgery in only one tooth

Intervention groups

In this study, Coe-Pak dressing will be applied after crown-lengthening surgery in half of the patients (intervention group), while no dressing will be applied in the other half (control group). Pain and wound healing will then be compared between the two groups.

Main outcome variables

Comparison of the intensity and duration of pain with and without Coe-Pak dressing Comparison of the mean Early Healing Index (EHI) score with and without Coe-Pak dressing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251204068211N1**
Registration date: **2025-12-11, 1404/09/20**
Registration timing: **prospective**

Last update: **2025-12-11, 1404/09/20**
Update count: **0**

Registration date

2025-12-11, 1404/09/20

Registrant information

Name

Pouria Batoei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 6734

Email address

pouriabatoei98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-19, 1404/09/28

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of non-eugenol periodontal dressing (Coe-Pak) on pain and wound healing after crown lengthening surgery

Public title

effect of Coe-Pak on pain and wound healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and older Ability to respond to the questionnaire items Informed consent to participate in the study Absence of systemic disease No contraindications for surgery Need for functional crown-lengthening surgery in only one tooth

Exclusion criteria:

Lack of willingness to continue cooperation during the study Failure to attend postoperative follow-up visits Improper completion of the forms Partial or complete loss of the periodontal dressing before the first follow-up appointment (7 days after surgery) Allergic reaction to the periodontal dressing Occurrence of pulpal changes after the surgical procedure

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, permuted block randomization will be used to generate the random allocation sequence for assigning participants to the study groups. The random allocation sequence will be created using the Random Allocation Software with a block size of two. Permuted block randomization is a method in which each block is selected with a size equal to the number of study groups. In this study, there are two possible blocks: AB and BA. One of the blocks will be randomly selected; if the first block (AB) is chosen, the first participant will be assigned to group A and the second participant to group B. This process will continue until all participants have been allocated. The advantage of this method is that it ensures equal sample sizes in both study groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be randomly assigned to two groups: the test group (with Coe-Pak dressing) and the control group (without Coe-Pak dressing). The surgical information of each patient will be placed in a sealed opaque envelope and handed to the surgeon by the surgical ward nurse. After the surgery is completed, the opaque envelope will be opened and the patient’s group allocation will be revealed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

thics committee of Mashhad University of Medical Sciences

Street address

Hashemie Blvd, 47 Hashemie

City

Mashhad

Province

Razavi Khorasan

Postal code

9178613357

Approval date

2025-10-29, 1404/08/07

Ethics committee reference number

1404.079

Health conditions studied

1

Description of health condition studied

Evaluation the effect of non-eugenol periodontal dressing (Coe-Pak) on pain and wound healing after crown lengthening surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Our primary outcome variable is pain assessment using the Visual Analog Scale (VAS). We will compare pain levels between individuals who receive a periodontal pack (Co-Pac) after crown-lengthening surgery and those who do no

Timepoint

Pain will be measured during the first 7 days following the crown-lengthening procedure

Method of measurement

pain will be measured using the Vas scales (0-10)

Secondary outcomes

1

Description
Presence of infection after surgery.
Timepoint
One week after the operation.
Method of measurement
Infection is evaluated based on the presence of swelling, redness, and pain

Intervention groups

1

Description
Intervention group: In the intervention group, after performing crown lengthening surgery and suturing, we apply periodontal Coe-Pak dressing according to the manufacturer's instructions and in an adequate amount over the surgical site for a duration of one week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Dentistry of School
Full name of responsible person
Pouria batoei
Street address
Vakil Abad Blvd , opposite of Mellat Park
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3806 7100
Email
Mail.support@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghidi
Street address
Vakill Abad Blvd , opposite of Mellat Park
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3806 7100
Email
Mail.support@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Pouria Batoei
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Hashemie Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9178613357
Phone
+98 51 3883 6734
Email
pouriabatoei98@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Pouria Batoei
Position
Student

Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Hashmie Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9178613357
Phone
+98 51 3883 6734
Email
pouriabatoei98@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Pouria Batoei
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Hashmie Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9178613357
Phone
+98 51 3883 6734
Email
pouriabatoei98@gmail.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