Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effects of a combined mouthwash of tranexamic acid and cetylpyridinium chloride in plaque reduction and bleeding control in patients undergoing crown lengthening surgery: A randomized, triple-blind clinical trial

Protocol summary

Study aim
Comparison of the efficacy of a combined mouthwash (TXA 5% + CPC 0.05%) versus 0.2% chlorhexidine mouthwash in controlling bleeding and reducing plaque following crown lengthening surgery

Design
Randomized, block, triple-blind, parallel, single-center, clinical trial

Settings and conduct
In the Department of Periodontology, Mashhad School of Dentistry, participants will be randomly assigned to two groups: intervention and control. Care providers, outcome assessors, and the data analyst are blinded.

Participants/Inclusion and exclusion criteria
Inclusion 18–70, ASA I–II, periodontal, no-antibiotic, no-antiseptic, no-anticoagulant, normal-coagulation, oral-hygiene, consent, follow-up Exclusion ASA ≥III, systemic-disease, coagulopathy, anticoagulant, pregnancy, lactation, allergy, oral-infection, poor-hygiene, interfering-drugs, incapacity

Intervention groups
Patients who use a combined mouthwash of tranexamic acid (5%) and cetylpyridinium chloride (0.05%) following crown lengthening surgery.

Main outcome variables
Presence or absence of bleeding, OLeary plaque index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260206068771N1**
Registration date: **2026-02-13, 1404/11/24**
Registration timing: **prospective**
Last update: **2026-02-13, 1404/11/24**
Update count: **0**

Registration date
2026-02-13, 1404/11/24

Registrant information

Name
Zahra sadat Riazi nia

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2026-03-31, 1405/01/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of a combined mouthwash of tranexamic acid and cetylpyridinium chloride in plaque reduction and bleeding control in patients undergoing crown lengthening surgery: A randomized, triple-blind clinical trial

Public title

Comparison of the effects of a combined mouthwash of tranexamic acid and cetylpyridinium chloride in plaque reduction and bleeding control in patients undergoing crown lengthening surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18–70 years Systemically healthy (ASA I–II) Requiring periodontal surgery following non-surgical treatment No use of antibiotics or antiseptic mouthwashes in the past 4 weeks No use of anticoagulants or medications affecting hemostasis in the past 10 days Normal coagulation status and platelet count· Acceptable oral hygiene following initial preparation Signed informed consent and ability to attend follow-up visits Smoking ≤10 cigarettes per day Controlled diabetes (HbA1c < 7%) Low plaque and bleeding scores in non-surgical areas No removable prostheses or active orthodontic appliances Acceptable oral hygiene following initial preparation

Exclusion criteria:

ASA ≥ III or uncontrolled systemic disease Coagulation disorders or inability to adjust anticoagulant therapy Pregnancy or breastfeeding Allergy to mouthwash ingredients Active oral infection or uncontrolled abscess Severe, non-modifiable poor oral hygiene Use of medications that may affect outcomes (corticosteroids, immunosuppressants) Lack of legal capacity or competence to participate Non-adherence to mouthwash use or follow-up visits Heavy smoking (>20 cigarettes/day) Development of new oral disease or inflammatory lesions Intraoperative complications such as abnormal bleeding or vascular rupture Serious medical adverse events during the study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Block randomization Software used: Random Allocation Software Type of randomization: Block Allocation concealment method: Sealed opaque envelopes An independent colleague not involved in study assessments prepares the block randomization allocation list using Random Allocation Software with alternating block sizes of 4 and 6. Allocation concealment: Group codes (A and B) are placed in opaque, sequentially numbered, sealed envelopes. These envelopes are opened by someone other than the assessor after the patient's enrollment is finalized and just before the intervention begins.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study was designed as a triple-blind randomized clinical trial. Participants, the surgeon, the outcome assessor, and the statistical analyst were all blinded to group allocation. To implement blinding, the mouthwashes were packaged by an individual outside the research team who was not involved in treatment, outcome assessment, or data analysis. The mouthwashes were placed in identical bottles in terms of shape, color, volume, and labeling. Each bottle was identified only by a unique code, and the code list was kept with the individual responsible for randomization and was not disclosed until after the statistical analysis was completed. Participants received mouthwashes based on the assigned codes and were unaware of the type of solution they used. The surgeon and the clinical assessor recording outcome measures also had no access to group allocation. Data recording forms contained only participant codes. Data collection was performed by a trained assessor who was blinded to treatment allocation. Statistical analysis was conducted using coded data by an analyst who had no knowledge of group identities..

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Dentistry University of Mashhad Medical Sciences

Street address

Dentistry University of medical Science, Beginning of the Vakilabad Boulevard, Mashhad

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Province

Razavi Khorasan

Postal code

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Approval date

2025-11-29, 1404/09/08

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1404.094

Health conditions studied

1

Description of health condition studied
Patients undergoing periodontal crown lengthening surgery
ICD-10 code
K05
ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
Percentage of dental surfaces with plaque based on OLeary plaque control record following the use of mouthwash after periodontal surgery.
Timepoint
Before intervention and seven days after initiation of mouthwash use following periodontal surgery
Method of measurement
Dental plaque is disclosed using a plaque disclosing agent and the percentage of tooth surfaces with plaque is calculated according to OLeary plaque control record by a calibrated examiner under standard clinical conditions..

2

Description
Presence or absence of bleeding after periodontal surgery. Bleeding is defined as either self-reported spontaneous bleeding in the past 7 days or observation of active bleeding or fresh blood clot at the surgical site during clinical examination.
Timepoint
Before surgery and 1 week after periodontal surgery
Method of measurement
Patient self-report questionnaire + clinical examination. Qualitative recording (Yes/No). If at least one condition is met, bleeding is recorded as "Yes"

Secondary outcomes

1

Description
Periodontal wound healing evaluated quantitatively using the Early Healing Index (EHI) ranging from 1 to 4 based on multiple clinical items.
Timepoint
1 week after periodontal surgery
Method of measurement
Visual and clinical examination by blinded examiner; scoring according to EHI criteria

2

Description
Patient adherence to mouthwash regimen, calculated as percentage of actual use over 7 days.
Timepoint
Daily recording for 7 days after surgery
Method of measurement
Patient self-reported questionnaire recording weekly and daily frequency of mouthwash use and duration of retention in the oral cavity.calculated as (actual doses taken / 7) × 100.

3

Description
Patient satisfaction
Timepoint
1 week after periodontal surgery
Method of measurement
Patient satisfaction assessed by combined quantitative and qualitative measures: - Quantitative: Visual analogue scale from 0 (completely dissatisfied) to 10 (completely satisfied). - Qualitative: Standardized questionnaire evaluating behavioral-attitudinal aspects (willingness to repurchase, recommend, or continue use).

4

Description
Occurrence of any adverse events after intervention (Yes/No).
Timepoint
1 week after periodontal surgery
Method of measurement
Patient self-report questionnaire + clinical examination. Reporting as percentage of patients experiencing each adverse event.

Intervention groups

1

Description
Intervention group:Participants receive a combination mouthwash containing Cetylpyridinium Chloride (CPC) and Tranexamic Acid (TXA) following periodontal surgery. The mouthwash is formulated by the Faculty of Pharmacy, Mashhad University of Medical Sciences. Patients are instructed to use 15 mL of the solution twice daily for 30 seconds, starting 24 hours after surgery, for a total duration of 7 days. The mouthwash is provided in identical coded bottles to maintain blinding.
Category
Treatment - Drugs

2

Description
Control group:Participants receive 0.12% chlorhexidine mouthwash following periodontal surgery. Patients are instructed to use 15 mL of the mouthwash twice daily for 30 seconds, starting 24 hours after surgery, for 7 days. The mouthwash is provided in identical coded bottles similar to the intervention group to maintain blinding.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Periodontal Department of Dentistry University Of Mashhad medical Science

Full name of responsible person
Ershad Aghasizadeh

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Sponsors / Funding sources

1

Sponsor

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Grant name
Vice Chancellor for Research, Mashhad University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Zahra sadat Riazi nia

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
اطلاعات بیشتری وجود ندارد

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Study protocol and final clinical study report The approved study protocol registered in IRCT and the final clinical study report published in a peer reviewed journal will be available. No individual participant data will be shared.

When the data will become available and for how long
The study protocol will be available upon registration in IRCT. The final clinical study report will be available after publication of the study results, with no time limitation.

To whom data/document is available
The study protocol and published report will be publicly accessible to researchers, clinicians, and academic institutions.

Under which criteria data/document could be used
Documents may be used for academic and research purposes with appropriate citation. Commercial use requires formal permission from the principal investigator and affiliated institution.

From where data/document is obtainable
The protocol is accessible via the IRCT registry website. The final report will be available through the published journal article. For further information, contact the principal investigator via institutional email.

What processes are involved for a request to access data/document
No formal application is required for accessing the protocol or published report. For commercial inquiries, written permission must be obtained from the principal investigator and institution.

Comments