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Study on gum healing in smokers using hyaluronic acid during surgery

Submission date
25/07/2025

Recruitment status
No longer recruiting

Registration date
04/08/2025

Overall study status
Completed

Last Edited
04/08/2025

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Crown lengthening is a common surgical procedure used to expose more of a tooth for restorative or cosmetic purposes. However, in people who smoke, healing after such surgery is often delayed due to the harmful effects of smoking on blood flow and tissue repair. This study aims to investigate whether applying a gel made of hyaluronic acid, a natural substance found in the body that supports wound healing, can help smokers heal faster and experience less discomfort after crown lengthening surgery. The study will compare healing outcomes between those who receive hyaluronic acid during surgery and those who do not.

Who can participate?
Adults aged 18 to 60 years who are current smokers (smoking 10 or more cigarettes per day) and are medically healthy may take part. Participants must be referred for a crown lengthening procedure at the College of Dentistry, King Saud University. Both men and women are eligible. People with certain medical conditions, pregnant or breastfeeding women, or those taking medications that could affect healing will not be able to take part.

What does the study involve?
Participants are randomly allocated to one of two groups. The study is double-blind, meaning neither the patient nor the person assessing healing will know which group the patient is in. One group will receive hyaluronic acid gel applied directly to the surgical site during crown lengthening. The other group will receive standard care without hyaluronic acid (a saline rinse will be used instead). Both groups will receive the same surgical procedure. The gel is applied once, during the surgery. After the procedure, participants will be monitored at 2 weeks and 6 weeks to assess healing and recovery.
The following measurements will be taken:
1. Wound healing, assessed using the Landry healing index
2. Pain levels, assessed using a visual analogue scale (VAS)
3. Gum health indicators, including probing depth, plaque index, gingival index, and bleeding on probing
4. Bone healing, assessed using x-rays taken before and after surgery

What are the possible benefits and risks of participating?
Participants may benefit from improved healing and reduced pain if the hyaluronic acid is effective. Participation also contributes to advancing dental care for smokers. The procedure involves minor surgical risks such as discomfort, swelling, or temporary bleeding, which are the same as standard treatment. Hyaluronic acid is safe and has been used widely in medical and dental applications, with minimal risk of allergic reaction.

Where is the study run from?
College of Dentistry, King Saud University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
April 2020 to September 2024

Who is funding the study?
This is an investigator-initiated and self-funded study, supported by the College of Dentistry at King Saud University. There is no external commercial funding.

Who is the main contact?
Dr Dalal AlOtaibi, dalalotaibi@ksu.edu.sa

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of local application of hyaluronic acid on wound healing after crown lengthening procedure in smokers: a double-blind randomized controlled clinical trial

Acronym
HA-WH

Study objectives
The local application of cross-linked hyaluronic acid during osseous crown lengthening improves wound healing and reduces postoperative discomfort in smokers

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/04/2020, Institutional Committee of Research Ethics (King Saud University, Riyadh, PO Box: 7805/Zip code: 11472, Saudi Arabia; +966 (0)11 467 00 11; aalsultan1@ksu.edu.sa), ref: 20/0416/IRB

Study design
Randomized controlled double-blind parallel-arm single-centre clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Post-surgical wound healing in smokers following periodontal crown lengthening

Interventions
Patients were randomly assigned in a 1:1 ratio to one of two groups using a computer-generated randomisation list. In the test group, cross-linked hyaluronic acid gel (hyaDENT BG, Bioscience, Germany) was applied directly to the root surfaces using a cartridge syringe with a 23G needle

immediately following osseous crown lengthening surgery. In the control group, the surgical protocol was identical, but instead of hyaluronic acid, a saline rinse was applied to the site. Each treatment was administered as a single application during surgery. All patients were followed up for 6 weeks postoperatively, with clinical parameters evaluated at 2 and 6 weeks. Both patients and outcome assessors were blinded to group allocation. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes.

Intervention Type
Biological/Vaccine

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Hyaluronic acid (cross-linked)

Primary outcome measure
Wound healing measured using the Landry healing index at 2 weeks and 6 weeks post-surgery

Secondary outcome measures
1. Pain measured using a visual analogue scale (VAS) at 2 weeks and 6 weeks post-surgery
2. Probing pocket depth (PPD) measured using a UNC-15 periodontal probe at baseline, 2 weeks, and 6 weeks post-surgery
3. Plaque Index (PI) measured using the Silness and Loe index at baseline, 2 weeks, and 6 weeks post-surgery
4. Gingival Index (GI) measured using the Loe and Silness index at baseline, 2 weeks, and 6 weeks post-surgery
5. Bleeding on probing (BOP) measured using dichotomous bleeding scores at baseline, 2 weeks, and 6 weeks post-surgery
6. Radiographic bone height measured using standardized vertical bitewing radiographs at baseline and 6 weeks post-surgery

Overall study start date
20/04/2020

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. Male or female
2. Aged between 18 and 60 years
3. Individuals in good general health with no systemic conditions affecting wound healing
4. Current smokers consuming 10 or more cigarettes per day

5. Referred for crown lengthening surgery
6. Able to understand the study and provide written informed consent
7. Willing and able to attend all scheduled follow-up visits at 2 and 6 weeks post-surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Individuals diagnosed with systemic conditions known to impair wound healing (e.g., uncontrolled diabetes, osteoporosis)
2. Pregnant or breastfeeding individuals
3. Recent use of systemic antibiotics or anti-inflammatory drugs within the past 2 months
4. Current use of medications that may alter periodontal healing, such as corticosteroids, immunosuppressants, or bisphosphonates
5. Presence of dental restorations that obstruct accurate probing depth measurements at the surgical site
6. Evidence of untreated active periodontal infection
7. Inability or not willing to provide written informed consent

Date of first enrolment
01/01/2021

Date of final enrolment
01/01/2023

Locations

Countries of recruitment
Saudi Arabia

Study participating centre

College of Dentistry, King Saud University
King Saud University
Prince Turki Al-Awal Street
Riyadh
Saudi Arabia
11545

Sponsor information

Organisation
King Saud University

Sponsor details
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Sponsor type
University/education

Website
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ROR
https://ror.org/02f81g417

Funder(s)

Funder type
University/education

Funder Name
College of Dentistry, King Saud University

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Dalal AlOtaibi (dalalotaibi@ksu.edu.sa)
Type of data that will be shared: Anonymised individual-level clinical data, including healing index scores, pain scores, periodontal measurements, and demographic information.
When the data will become available: After publication of the main study findings.
How long the data will be available for: For up to 5 years following publication.
Access criteria: Data will be shared with qualified researchers upon reasonable request for academic, non-commercial research purposes. Requests will be reviewed by the study team to ensure ethical and scientific use.
Mechanism for data sharing: Data will be shared electronically via secure email or institutional repository after signing a data use agreement.
Consent and anonymisation: Participant consent for data sharing was obtained. All shared data will be fully anonymised.
Ethical/legal restrictions: Data sharing will comply with institutional ethical approvals and relevant data protection regulations.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/08/2025	No	No
Statistical Analysis Plan			04/08/2025	No	No