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Investigating how well a turmeric extract gel helps in wound healing after the surgical removal of gingival pigmentation

Submission date
25/11/2024

Recruitment status
No longer recruiting

Registration date
29/11/2024

Overall study status
Completed

Last Edited
29/11/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
This study aimed to prepare turmeric extract gel with a concentration of 10% and compare it with a non-eugenol periodontal dressing (Coe-Pak) after the surgical removal of gingival pigmentation (black gums). This was carried out by evaluating wound healing, pain, the number of painkillers taken, bleeding on probing, plaque and the patient's esthetic and surgical satisfaction.

Who can participate?
Patients aged over 18 years with gingival pigmentation and good oral health

What does the study involve?
The study involves the removal of gingival pigmentation by a surgical scalpel on the upper jaw. The surgical procedure was performed in two phases, a week apart, and either the conventional dressing or the turmeric extract gel were applied.

What are the possible benefits and risks of participating?
The potential benefits of participating in this study are esthetic and the potential risks are almost non-existent.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2023 to March 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Nadia Dibeh, dibehnadia@gmail.com

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Efficiency evaluation of applying curcuma longa extract gel as a dressing after surgical gingival depigmentation

Study objectives

Turmeric extract gel is expected to reduce post-operative pain, the number of analgesics taken by the individuals, bleeding on probing, plaque accumulation, enhance the healing process of the wound and re-epithelialization, and improve patient's esthetic and surgical satisfaction, compared to coe-pak dressing.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/05/2023, Damascus University - Faculty of Dental Medicine (Almazah, Damascus, Nil known, Syria; +963 (0)113341864; manger@hcsr.gov.sy), ref: 223445

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with bilateral class 3 or 4 of Hedin's classification of gingival pigmentation

Interventions
Gingival depigmentation was performed by a surgical scalpel in a split-mouth manner on the upper jaw of the research sample. The surgical procedure was performed in two phases, a week apart, and both the Coe-Pak and the turmeric extract gel 10% were applied to a randomly selected side using the coin toss method.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain measured using a Visual Analogue Scale (VAS) 0-100 and by recording the number of analgesics taken by the individuals at baseline, on the day of surgery and daily from post-surgical day 1 to 7
2. Wound healing assessment the Wound Healing Index (WHI) at 1, 2, 3, and 4 weeks post-surgery

Key secondary outcome(s))
The following secondary outcome measures are assessed at 1, 2, 3, and 4 weeks post-surgery:
1. Re-epithelialization index measured using toluidine blue and image J program
2. The patient's oral health measured using bleeding on probing index (BOP), plaque index (PI)
3. Patient satisfaction measured using a Visual Analogue Scale (VAS) 0-100

Completion date
08/03/2024

Eligibility

Key inclusion criteria
1. Good general health
2. There are no contraindications to periodontal surgery
3. Patients with bilateral, physiologic gingival pigmentation in the buccal maxillary gingiva, classified as class 3 or class 4 according to Hedin's classification
4. Good oral health: PI <1, BOP <10%
5. All patients are over 18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Patients with systemic diseases or conditions associated with gingival pigmentation and could affect healing and coagulation
2. Drugs intake, especially those associated with gingival pigmentation
3. Periodontal diseases
4. Smokers and alcoholics
5. Pregnancy and lactation

Date of first enrolment
22/08/2023

Date of final enrolment
30/01/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Periodontology Faculty of Dental Medicine
Mazzah
Damascus
United Kingdom
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Prof. Dr Rowaida Saymeh (rowaidah.saymeh@damascusuniversity.edu.sy). All of the patients' data will be available upon request. Consent was obtained from the participants.

IPD sharing plan summary

Available on request