

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/11/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Type(s)

Scientific, Principal investigator

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Additional identifiers

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