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

Submission date	Recruitment status	Prospectively registered
25/11/2024	No longer recruiting	[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
29/11/2024	Completed	[_] Results
Last Edited	Condition category	Individual participant data
29/11/2024	Oral Health	[X] 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

Contact name Dr Nadia Dibeh

ORCID ID http://orcid.org/0009-0002-3654-546X

Contact details Almazzeh Damascus Syria -+963 (0)45196074 nadia3.dibeh@damascusuniversity.edu.sy

Type(s) Public

Contact name Prof Rowaida Saymeh

Contact details Almazzeh Damascus Syria

+963 (0)933348834 rowaidah.saymeh@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

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

Study type(s) Treatment

Participant information sheet No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

15/03/2023

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

Age group Adult

Lower age limit 18 Years

Upper age limit 50 Years

Sex

Both

Target number of participants 12 patients (24 sites)

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

Periodontal diseases
Smokers and alcoholics
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

Sponsor information

Organisation Damascus University

Sponsor details Albaramka Damascus Syria -+963 (0)1133923192 info@damascusuniversity.edu.sy

Sponsor type University/education

Website http://www.damascusuniversity.edu.sy

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

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

Intention to publish date 10/12/2024

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