ISRCTN69571802 https://doi.org/10.1186/ISRCTN69571802

# 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

# 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

### Primary study design
Interventional

### Study design
Interventional randomized controlled trial

### 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