

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

<b>Submission date</b> 25/11/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/11/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/11/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" 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](mailto:dibehnadia@gmail.com)

## Contact information

### Type(s)

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

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

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

**Sponsor details**

Albaramka

Damascus

Syria

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**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