

Study of the therapeutic effects of curcumin gel after gum repair surgery

Submission date 15/12/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/12/2020	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

Free gingival grafts – when healthy tissue from the roof of your mouth is attached to your teeth where the root is exposed can prevent any further loss of gum tissue and it can help with sensitivity.

The spice turmeric contains a substance called curcumin, which has long been used in Asian medicine and is linked to health benefits.

This study aims to evaluate the therapeutic effect of curcumin extract and comparing using it or gingival dressing after grafting surgery.

Who can participate?

Healthy adults aged 18 - 45 years who are non-smokers

What does the study involve?

Piece of gum will be grafted and sutured for each group. One group will receive curcumin gel and the other will receive gingival dressing. The size of the grafts, their healing and the patient's pain will be assessed afterwards.

What are the possible benefits and risks of participating?

Both are safe and should not cause any additional risks, other than those involved in the gum grafting procedure. All participants will receive the same treatment.

Where is the study run from?

Damascus University (Syria)

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

October 2020 to January 2022

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Zuhir Alasfar, zuhiralasfar@gmail.com

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

3078

Study information

Scientific Title

Evaluation of the usage of extracted curcumin in the healing of free gingival graft and donor site palatal wound

Study objectives

To test the therapeutic effect of curcumin extracted gel, and comparing it to gingival dressing after free gingival graft surgery

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 09/10/2020, Ethics Committee- Dental College- Damascus University (MazzeH Highway, Damascus, Syria; +963 1133923486; sr.srd@damasuniv.edu.sy), ref: no.3889

Study design

Single centre clinical comparative randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Free gingival (gum) treatment for absence or insufficiency of attached gingiva

Interventions

All participants undergo free gingival graft surgery

In the test group, we will apply curcumin gel in the donor and recipient site for 7 days after surgery.

In the control group, we will apply gingival dressing in the donor and recipient site.

The size of the grafts, their healing and the patient's pain will be assessed afterwards for 3 months.

Randomization method: flipping a coin.

Intervention Type

Supplement

Primary outcome(s)

Shrinkage of the graft assessed using at 2 months, 3 months and 6 months. A standard sizing template of known size is placed beside the graft and digital photographs are taken. Software is used to calculate the size of the graft by comparing it with the template in the images

Key secondary outcome(s)

1. Shrinkage of the graft assessed using at 2 months, 3 months and 6 months
1. Recipient site healing assessed using the modified early-wound healing index (MEHI) at 1 week, 2 weeks, 1 month and 2 months
2. Recipient site pain assessed by the patient using a 1-10 visual analogue scale at 6 h, 12 h, 24 h, 2 days, 3 days, 4 days, 5 days, 6 days and 7 days after surgery

Completion date

01/01/2022

Eligibility

Key inclusion criteria

1. Attached gingiva ≤ 1 mm
2. No systemic diseases
3. Non-smoker
4. Gingival inflammation and plaque indexes $< 20\%$ at time of surgery
5. Aged 18 - 45 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Systemic disease that would interfere with the healing process
2. Has undergone previous periodontal surgery
3. Tooth mobility
4. Pregnant
5. Radiation-exposed
6. Alcoholic
7. Receiving diuretic treatment
8. Taking hormone alternatives
9. Immunocompromised

Date of first enrolment

02/12/2020

Date of final enrolment

01/12/2021

Locations

Countries of recruitment

Syria

Study participating centre

Damascus Univesity

Department of Periodontology

Mazzah High Way

Damascus

Syria

DM20AM18

Sponsor information

Organisation

Damascus University

ROR

<https://ror.org/03m098d13>

Funder(s)**Funder type**

University/education

Funder Name

Damascus University

Results and Publications**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other