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

Submission date 15/12/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/12/2020	**Overall study status** Completed	
Last Edited 24/12/2020	**Condition category** Oral Health	

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

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Additional identifiers

Clinical Trials Information System (CTIS)
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 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