

A comparison between a typical dressing and an absorbed dressing after surgical removal of gum pigmentation

Submission date 24/01/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/09/2020	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

Gum pigmentation (gingival pigmentation) is caused by melanin and melanin is a natural substance in the body that is found in freckles, sun spots, age spots. Some people have an overproduction of melanin in their gums. Discoloration may also be caused by long term use of certain medications.

Proper healing is a must for a successful periodontal surgery. Many new dressings are made and tested to reach a perfect dressing to insure complete and fast wound healing. The absorbed (cellulose-based) dressing (Reso-Pac) is the newest dressing. In this study, it is compared with the traditional dressing (Coe-Pack) in healing wounds.

Who can participate?

Healthy patients aged 18 – 40 years who have gingival pigmentation.

What does the study involve?

After surgical removal of gingival pigmentation, participants will receive two different types of wound dressing, one on each side of the mouth. Healing will be assessed for three weeks after the surgery.

What are the possible benefits and risks of participating?

The benefit is the potential for faster healing. The risks will be to have an allergic reaction towards the new dressing

Where is the study run from?

Damascus University Department of Periodontology (Syria)

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

November 2019 to January 2021.

Who is funding the study?

Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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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
A comparison between eugenol-free dressing (Coe-Pack) and absorbed dressing (Reso-Pac) after surgical removal of gingival pigmentation (spilt mouth study)

Study objectives
The new cellulose-based dressing (Reso-Pac) will be more successful in healing wounds compared to the traditional dressing (Coe-Pack)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/6/2019, Damascus University Ethics Board (MazzeH Highway, Damascus, Syria; +963 1133923486; sr.srd@damasuniv.edu.sy), ref: co2733

Study design

Split mouth randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Gingival melanosis

Interventions

Surgical removal of gingival pigmentation on the maxillary using surgical scallop and putting the absorbed dressing Cellulose based (reso-pac) randomly on one side and the typical eugenol-free dressing (Coe-pak) on the other side.

Randomisation: a coin is used to determine which side to put the absorbed dressing (Reso-pac) and the eugenol-free dressing (Coe-pack)

Patients were followed up for three weeks after surgery.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Pain: each day for 1 week post-surgery using VAS (scale 0-100)
2. Induced pain: 1 week after surgery using air abrasion of 5 seconds on every side using VAS (scale 0-100)
3. Epithelial re-formation: using blue toluidine in 1 week, 2 weeks, 3 weeks after surgery
4. Healing: using Lundry Healing index Criteria (1988) 1 week, 2 weeks, 3 weeks after surgery

Secondary outcome measures

Time (s) of dressing application measured using a stopwatch

Overall study start date

20/04/2019

Completion date

15/01/2021

Eligibility

Key inclusion criteria

1. Healthy patient with gingival pigmentation grade 3 and 4 on the maxillary
2. Aged between 18 - 40 years
3. Good oral hygiene

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

10 patients (20 surgical site 2 for each patient)

Key exclusion criteria

1. Systematic disease and hormone disorder
2. Medication that could lead to gingival pigmentation
3. Periodontitis
4. Smokers
5. Pregnant and breastfeeding

Date of first enrolment

19/11/2019

Date of final enrolment

20/12/2020

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Department of Periodontology

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Sponsor information

Organisation

Damascus University

Sponsor details

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Sponsor type

University/education

Website

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Funder(s)

Funder type

University/education

Funder Name

Damascus University

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

15/01/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request