ISRCTN76318940 https://doi.org/10.1186/ISRCTN76318940

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

Registration date
11/02/2020

Overall study status
Completed

Last Edited
11/09/2020

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
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?
Dr Rudwan Kazwini
rudwan-den@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Rudwan Kazwini

Contact details
Mashrou Dummar Jazereh 19 Al-Ameen building
Damascus
Syria
00000
+963 932652958
rudwan-den@hotmail.com

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
Mazzah Highway
Damascus
Syria
00000

Sponsor information

Organisation
Damascus University

Sponsor details
Alabaramkeh
Damascus
Syria
00000
+963 1133923192
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

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