ISRCTN36733842 https://doi.org/10.1186/ISRCTN36733842

Evaluation of Gelclair® (intraoral gel) application after the surgical removal of black unaesthetic gum

Submission date
11/11/2022

Recruitment status
No longer recruiting

Registration date
13/01/2023

Overall study status
Completed

Last Edited
13/01/2023

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
Black-coloured gums (gingival pigmentation) are a huge aesthetic concern for many individuals, especially for those who have more visible gums during smiling. The gold standard to remove this pigmentation is using a surgical blade which causes an open wound that requires management to prevent pain and infection through applying a protective dressing. The traditional dressing (COE-PAK) has many downsides as it is unstable, unaesthetic and does not promote healing. Gelclair is a therapeutic gel that can be used for healing oral mucosa inflammation after the treatment of gingival pigmentation. For patients with gingival pigmentation, this study aims to assess the effect of Gelclair in comparison to a traditional gingival dressing (COE-PAK) at improving soft tissue healing after the treatment.

Who can participate?
Healthy adults with gingival pigmentation

What does the study involve?
This study involves using surgical treatment of gingival pigmentation using a blade and applying a COE-PAK dressing on one side and Gelclair on the other side.

What are the possible benefits and risks of participating?
Gingival depigmentation can provide the desired aesthetic outcome but may cause some pain and discomfort. Using Gelclair may reduce pain and promote healing after surgical gingival depigmentation.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
March 2021 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lynn Amasha
Lynn.Amasha@gmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Dr Lynn Amasha

ORCID ID
https://orcid.org/0000-0002-1405-1998

Contact details
Jaramana
Ghassan Kanafany Street
Damascus
Syria
0000
+963 (0)949382544
lynn.amasha@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Efficiency evaluation of applying sodium hyaluronate postoperative surgical gingival depigmentation

Study objectives
Gingival pigmentation is considered a main common aesthetic concern. Gingival depigmentation procedures can cause pain and discomfort for patients. Gelclair® is a pharmacological material

that is used to manage pain and reduce the healing period for mucositis patients after cancer therapy. This study is designed to evaluate the role of applying Gelclair® in reducing pain and healing time postsurgical depigmentation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study is registered at Damascus University in order to get a Master's degree in periodontology. This study did not require ethical approval because the treatment provided is considered a basic treatment for gingival pigmentation and the material used is internationally validated. However, ethical approval is now available.

Approved 01/06/2022, the Medical Trial Ethics Council (MTEC) in Damascus University (PO Box 30621, Damascus, Syria; +963 (11) 339 23223; dl.srd@damascusuniversity.edu.sy), ref: DN-01062022-5

Study design
Interventional 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 to request a participant information sheet

Health condition(s) or problem(s) studied
Reducing pain and healing time after surgical gingival depigmentation

Interventions
Randomization takes place through the “flip of a coin” method. The first time is to determine the treatment that will take place in the first week (test or control group), and the second time is to determine the side of the maxilla that will be treated first (since this is a split-mouth study).

The study contains two groups:
The test group: Gelclair dressing
The control group: Coe-Pak dressing

Day 1: removal of the gingival pigmentation of one side of the maxilla. Using a shaving motion, a number 15 blade is used to depigment the gingiva. Then a gingival dressing is applied (either Gelclair or Coe-Pak). The patient is provided with a sheet of paper that contains an assessment

for the degree of pain (using Visual Analog Scale [VAS]) to record the pain at 2 and 24 hours, and 2, 3, 4, 5, 6, and 7 days after the surgery.

Note: Gelclair is applied locally after the surgery, and then the patient is instructed to apply the gel four times daily for 1 week. On the other hand, Coe-Pak dressing is applied after the surgery and removed after 1 week.

After 1 week: the surgical removal of the pigmentation will be performed on the other side. Then the other gingival dressing is applied.

This study contains three indices for each study group:
1. Wound Healing Index: after 1, 2, 3, and 4 weeks of the surgery
2. Epithelialization test: after 1, 2, 3, and 4 weeks of the surgery
3. Pain Index: 2 and 24 hours and 2, 3, 4, 5, 6, and 7 days after the surgery

Intervention Type
Procedure/Surgery

Primary outcome measure
Healing of the soft tissues measured using the Wound Healing Index at the first, second, third, and fourth weeks

Secondary outcome measures
1. Epithelization formation measured using the Epithelization test at the first, second, third, and fourth weeks
2. Pain measured using a visual analogue scale (VAS) after the anaesthetic effect and every day for a week

Overall study start date
01/03/2021

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Class II or III of Hedin's index of gingival pigmentation
2. The absence of any periodontal infliction
3. Good width of attached gingiva
4. The absence of systemic diseases

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Total final enrolment
12

Key exclusion criteria
1. Gingival pigmentation as a manifestation of systemic diseases
2. Gingival pigmentation as a side effect of medication consumption
3. Systemic diseases that interfere with the healing of periodontal tissues (diabetes, hyperparathyroidism, etc)
4. Life-threatening diseases
5. Periodontal disease
6. Pregnancy or breastfeeding
7. Smokers
8. Patients who showed no sign of corporation in terms of good oral hygiene
9. Radiation therapy
10. Alcoholics
11. Drugs that interfere with periodontal healing

Date of first enrolment
01/11/2021

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dental Medicine
Periodontology Department
PO Box 30621
Damascus
Syria
0000

Sponsor information

Organisation
Damascus University

Sponsor details
PO Box 30621
Damascus
Syria
0000
+963 (0)11 339 23223
dl.srd@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/03/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication