

Investigating how well a new type of covering for the gums, called periodontal dressing, helps in the healing of wounds on the roof of the mouth

Submission date 02/03/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/03/2024	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

Gingival recession also known as receding gums, is defined as the apical displacement of the gingival margin in relation to the cemento-enamel junction (CEJ). The usage of connective tissue graft (CTG) with the Coronally Advanced Flap (CAF) is considered the gold standard for gingival recession and root coverage treatment. However, this technique requires a secondary surgical site, which can increase the postoperative pain.

The aim of this study is to evaluate the efficacy of using an attachable periodontal dressing (Ora_Aid) to protect the injury from mechanical harm, postoperative bleeding, or inflammation and to alleviate postoperative pain.

Who can participate?

Healthy adults aged 19 and over who are non-smokers.

What does the study involve?

Participants are randomly allocated to one of two treatment methods. One involves applying the gingival graft (CTG) with Coronally advanced flap (CAF), followed by applying the adhesive periodontal dressing on the donor site of the graft in the palatal area and over the flap. While the other involves applying (CAF) with (CTG) without applying dressing.

What are the possible benefits and risks of participants?

The possible benefits for participants are achieving less postoperative pain and better healing. The methods are safe and there are no expected risks.

Where is the study run from?

Damascus University (Syria)

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

May 2022 to December 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Remaz Abd Alkader, rymazoad@gmail.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Remaz Abdalkader

Contact details

Dumar

Damascus

Syria

-

+963(0)951753797

rymazoad@gmail.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Evaluation of the effect of attachable periodontal wound dressing (Ora-Aid) In the healing of the soft tissue during gingival recession treatment

Study objectives

The dressing is expected to alleviate the Patient's pain sensation and enhance the healing process of the palatal wound.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 09/05/2022, Damascus university - faculty of dental medicine (Damascus-Almazah, Damascus, -, Syria; +963113341864; manger@hcsr.gov.sy), ref: 223445

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Bilateral class I or II of Miller classification of gingival recession.

Interventions

Participants are randomly assigned using a sealed envelope method.

Two treatment methods will be implemented.

The first will involve applying a connective tissues graft (CTG) with a coronally advanced flap (CAF) and managing the donor site in the palatal by suturing, while the second will involve applying the connective tissue graft (GTG) with the Coronally advanced flap (CAF) with applying an adhesive periodontal dressing (Ora_Aid) on the donor site in palatal and over the Flap.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Pain using the visual analogue scale (VAS) 0-100 at 1 week after surgery
2. Wound healing assessment (Landry et al., 1988) at 1,2,3,4 weeks after surgery

Secondary outcome measures

1. Keratinized tissue width measured from gingival margin to mucogingival junction with the help of periodontal probe (UNC 15 probe) at baseline 1 and 3 months
2. Epithelization test at baseline 1 and 3 months
3. Relative attachment level measured using (UNC 15 probe) at baseline 1 and 3 month
4. HEALING INDEX (Huang, Neiva, & Wang, 2005) at baseline 1 and 3 months

Overall study start date

09/05/2022

Completion date

09/12/2023

Eligibility

Key inclusion criteria

1. Good general health.
2. There are no contraindications to periodontal surgery.
3. Complaint of receding gums at least in the upper jaw and/or mandible.
4. All Recessions of class I OR II Miller.
5. The appearance of the Cementoenamel junction in the teeth that need to cover the root.
6. All patients achieve adequate control of the microbial plaque.
7. All patients are over 18 years old.
8. The patient has not been subjected to any surgery around the tooth in the area to be worked on

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

20 sites (10 for each group)

Key exclusion criteria

1. Previous periodontal surgery
2. Use of any drug that might affect periodontal health
3. Tooth mobility ,bruxism
4. Patients with a history of malignancy

Date of first enrolment

01/10/2022

Date of final enrolment

10/10/2023

Locations

Countries of recruitment

Syria

Study participating centre

Damascus university Department of periodontology faculty of dentistry

Mezzah

Damascus

Syria

-

Sponsor information

Organisation

Damascus University

Sponsor details

Albaramka

Damascus

Syria

-

+963(0)1133923192

info@damascusuniversity.edu.sy

Sponsor type

University/education

Website

<https://damasuniv.edu.sy>

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are/will be available upon request from prof. Dr Tarik Kasim (prof.tarekkasem@hotmail.com)

All of data of the patients will be available on request.

Consent from participant was obtained.

IPD sharing plan summary

Available on request