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Effect of hyaluronic acid on the oral mucosa healing after diode laser biopsies

Submission date	Recruitment status	[_] Prospectively registered
29/08/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/09/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2024	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Oral mucosa can be affected by lesions which interfere with many functions such as eating, speaking, and swallowing. Oral fibroma is one of these lesions that appears commonly in the oral cavity. It is the most common reactive lesion in the oral cavity. Fibroma results from a chronic repair process that includes granulation tissue and scar formation resulting in a fibrous submucosal mass. This lesion doesn't have a risk of malignancy transformation. The most common sites in the oral cavity are the tongue, buccal mucosa, and lower labial mucosa. An excisional biopsy is the treatment choice for irritation fibroma, either by surgical scalpel, electric scalpel, cryosurgery, or diode laser. Diode laser based on many studies is a very sufficient way of taking excisional biopsies, however, it has a thermal effect on the oral mucosa that affects mucosal healing, which makes it take longer to heal compared to the surgical conventional way. Accordingly, hyaluronic acid (HA) is now used to accelerate the mucosal healing process after excision using lasers in general.

Who can participate?
Patients aged between 20 and 40 years old who have oral fibroma and systemic diseases free

What does this study involve?
Participants are randomly allocated into three groups: Group A (HA gel + diode laser), Group B (HA mouthwash + diode laser), and Group C (control group, diode laser only). HA use instructions are given to the first two groups, and oral hygiene instructions are given to all groups.

What are the possible benefits and risks of participating?
Benefits may include healing acceleration due to the HA application after taking the excisional biopsy of the oral fibroma using a diode laser.

Possible risks might be experiencing some pain and discomfort after taking the biopsy, and a slow healing process due to the thermal effect of the diode laser and the ineffectiveness of the HA.

Where is the study run from?
Damascus University, Syria

When is the study starting and how long is it expected to run for?
June 2023 to October 2025

Who is funding the study?
Damascus University, Syria

Who is the main contact?
Dr. Amr Alyafi, amr.alyafi@hotmail.com, amr.alyafi97@damascusuniversity.edu.sy

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
5289

Study information

Scientific Title
Studying the effect of hyaluronic acid on mucosal healing after excisional oral biopsies with 810 nm diode laser

Study objectives

h0: There are no statistical differences between the three studied groups. (HA gel group, HA mouthwash group, and only diode laser group)
h1: There are statistically significant differences between the three studied groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/08/2023, Scientific Ethics Committee at Damascus University (Baramkeh, Damascus, 4671, Syria; +9631133923223; ap.srd@damascusuniversity.edu.sy), ref: 3437

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Other, Treatment, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Mucosal healing after oral excisional biopsies

Interventions
This study is designed to evaluate the effect of hyaluronic acid (HA; Mouthwash - Gel) on mucosal healing after oral excisional biopsies with an 810 nm diode laser.

A simple method of randomisation is used that involves writing the group name (A, B, C) on a piece of paper inside three envelopes, and letting the patient choose the envelope randomly.

A brief methodology for each treatment arm:
-Group A (HA gel group + diode laser):
After taking the excisional biopsy with a diode laser (with parameters of 810 nm, 4W) which takes approximately less than 5 minutes, the patients will be given topical hyaluronic acid gel 0.2% to apply on the wound 3 times daily for 10 days. After each appliance, the patient should not eat or drink for an hour.

-Group B (HA mouthwash group + diode laser):
After taking the excisional biopsy with a diode laser (with parameters of 810 nm, 4W) which takes approximately less than 5 minutes, the patients will be given hyaluronic acid mouthwash 0.025% to rinse with 3 times daily out of brushing times for 10 days, by keeping it for a minute in

the mouth and then spitting it out. After each rinsing the patient should not eat or drink for an hour.

-Group C (diode laser only):
After taking the excisional biopsy with a diode laser (with parameters of 810 nm, 4W) which takes approximately less than 5 minutes, the wound will be left to heal spontaneously without allying any drug.

Percentage healing index (PHI: is an index that helps determine the healing process by taking a picture of the excision wound after the procedure immediately and after every follow-up visit, and then using the Adobe Photoshop application on PC to measure the excision wound area in square millimeters.

Intervention Type
Procedure/Surgery

Primary outcome measure
Excision wound area measured using the Percentage Healing Index (PHI) after the excision immediately (T0), at day 4 (T1), week 1 (T2), week 2 (T3), and 1 month (T4)

Secondary outcome measures
Pain is measured using a Visual Analogue Scale (VAS) at day 4, week 1, week 2, and 1 month

Overall study start date
24/06/2023

Completion date
24/10/2025

Eligibility

Key inclusion criteria
1. Patients that have oral fibromas on the non-keratinized oral mucosa
2. Excisional biopsy wounds with a diameter of less than 10mm

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. People who have systemic diseases
2. Smokers
3. Alcoholics

Date of first enrolment
01/07/2023

Date of final enrolment
01/07/2025

Locations

Countries of recruitment
Syria

Study participating centre
Oral Medicine Department, Faculty of Dental Medicine, Damascus University
Mezzeh highway
Damascus
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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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 peer-reviewed journal

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The data sets will be generated and analyzed during the current study and will be available upon request from Amr Alyafi, amr.alyafi@hotmail.com, amr.alyafi97@damascusuniversity.edu.sy

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			02/09/2024	No	Yes
Participant information sheet			02/09/2024	No	Yes