

# Removing an abnormal maxillary labial frenum (a small band of tissue that connects the upper lip to the gums) using a scalpel and laser

<b>Submission date</b> 09/11/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/11/2023	<b>Condition category</b> 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

The frenum is a fold in the mucous membrane that connects the lip and the cheek to the tissues around the upper teeth. When these folds, called frena, are too closely attached to the gum line, it can potentially impact gum health. This can happen due to issues like difficulty in cleaning plaque or tension from muscle pull.

The aim of this study is to evaluate the pain and reinsertion of the frenum following conditional and laser assisted treatment in patients with abnormal upper labial frenum.

### Who can participate?

Patients aged 15 years and over with abnormal upper labial frenum

### What does the study involve?

Frenectomy with classical surgery and laser surgery and follow up for 3 months

### What are the possible benefits and risks of participating?

Decrease the pain and promote the healing of the wounds and make the patients more comfort  
The methods are safe and there are no expected risks.

### Where is the study run from?

Damascus University (Syria)

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

January 2021 to November 2023

### Who is funding the study?

Damascus University (Syria)

### Who is the main contact?

Dr Aisha Sayed Taha

Aysha.sayed.taha@gmail.com

# Contact information

## Type(s)

Public, Scientific, Principal Investigator

## Contact name

Dr Aisha Sayed Taha

## ORCID ID

<https://orcid.org/0009-0009-8580-2320>

## Contact details

Mazzeh

Damascus

Syria

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+963 (0)994778168

[aisha94.taha@damascusuniversity.edu.sy](mailto:aisha94.taha@damascusuniversity.edu.sy)

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

21/S.M

# Study information

## Scientific Title

A comparative clinical study between conventional surgical technique and different types of laser for frenectomy procedure

## Study objectives

There is no difference between laser assisted technique and conventional technique for Frenectomy

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 04/01/2021, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, -, Syria; +963 (0)1133923192; [ap.srd@damascusuniversity.edu.sy](mailto:ap.srd@damascusuniversity.edu.sy)), ref: None provided

**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**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Frenectomy in patients with abnormal labial frenum

**Interventions**

In this study, individuals with abnormal maxillary labial frenum were randomly treated with a conventional technique and different types of laser. Clinical measurements will be taken every month during the 3-month follow-up period.

1st group: conventional surgical technique

2nd group: conventional surgical technique followed by application diode laser 808nm for photobiomodulation

3rd group: laser Er:YAG for surgery

4th group: laser Diode 810nm for surgery

Follow up after one week, one month, 3months

Randomization by website:

[www.random.org](http://www.random.org)

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Pain is measured using a numerical scale (NS) at baseline, 24, 48, and 72 h.

**Secondary outcome measures**

1. Reepithelialization assessment by H2O2 after one week, two weeks, three weeks, 1 month, 3 months.

2. Reinsertion of the frenum by UNC15 probe after 1 month, 3 months.

**Overall study start date**

05/01/2021

**Completion date**

05/11/2023

## Eligibility

**Key inclusion criteria**

1. Systemically healthy
2. Non smoker
3. Between 15 and 55 years old
4. Not received any periodontal treatment within the last 3 months
5. Presence of at least central incisors, lateral incisors, and canines at the maxilla
6. Consent to participate in the study

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

15 Years

**Upper age limit**

55 Years

**Sex**

Both

**Target number of participants**

4 groups, 10 patient in each group

**Total final enrolment**

40

**Key exclusion criteria**

1. Any systematic disease that might interfere with wound healing process (i.e., diabetes mellitus and HIV infection)
2. Smoking
3. Antibiotics, anti-inflammatory drugs, or any other medication taken within the last 6 months that might affect the outcome of the study
4. Any hypersensitivity reactions against to paracetamol
5. Any physical limitations or restrictions that might preclude normal oral hygiene procedures

**Date of first enrolment**

01/10/2021

**Date of final enrolment**

05/08/2023

## Locations

## **Countries of recruitment**

Syria

## **Study participating centre**

### **Damascus University**

Department of Periodontology

Faculty of Dentistry

Mezzah

Damascus

Syria

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## **Study participating centre**

### **Damascus University**

High institute for Laser researches and applications

Faculty of mechanical and electrical engineering

Airport road

Damascus

Syria

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## **Sponsor information**

### **Organisation**

Damascus University

### **Sponsor details**

Albaramkeh

Damascus

Syria

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+963 (0)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

## 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

30/12/2023

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Wael Almahdi (w.almahdi76@gmail.com). All of data of the patients will be available on request.

Consent from participants was obtained.

## IPD sharing plan summary

Available on request