

# Modifying the characteristics of the gums using two different approaches

<b>Submission date</b> 05/07/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/08/2023	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Recently, more studies are addressing the importance of determining the characteristics of the gums (gingival phenotype) before dental procedures, as it has a significant impact on the outcome of restorative and regenerative therapy.

The aim of this study is to evaluate the change in gum thickness, and width of gum tissue that is keratinized, after treatment with either hyaluronic acid or injectable platelet rich fibrin.

### Who can participate?

Individuals with a thin gingival phenotype can participate in this study.

### What does the study involve?

Participants will be treated with hyaluronic acid (HA) on one side of the mouth and with injectable platelet rich fibrin (I-PRF) on the other. The side of the mouth on which each of the treatments will be received will be allocated at random (like tossing a coin) for all participants. The treatments will be injected into the gum on the front of the lower jaw. Injections will be given for 3 sessions with 7 days intervals.

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

Both HA and I-PRF promote regeneration, wound healing, and revascularization improved blood flow), and can possibly enhance the gingival phenotype by increasing thickness, and keratinized tissue width of the gums.

### Where is the study run from?

Damascus University (Syria)

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

From June 2020 to January 2022

### Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Nai Faour

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Clinical comparative study of hyaluronic acid versus I-PRF to modify the gingival phenotype

### Study objectives

1. Injecting hyaluronic acid increases gingival thickness more than I-PRF
2. Injecting hyaluronic acid increases keratinized tissue width more than I-PRF

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 24/08/2020, Scientific Research and Postgraduate Studies Council of Damascus University (Damascus, Syria 80789; +963 993303359; info@damascusuniversity.edu.sy), ref: 2793

## **Study design**

Interventional single-center single-blinded randomized split-mouth controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Thin gingival phenotype

## **Interventions**

In this split-mouth study, individuals with thin gingival phenotypes were randomly treated with hyaluronic acid and I-PRF. Allocation will be at random using a sequentially numbered opaque, sealed envelope method. HA will be injected in the gingiva on one side of the mandibular anterior region, and I-PRF will be injected on the other side for the same patient, for 3 sessions with 7 days intervals. Clinical measurements will be taken every month during the 3-month follow-up period.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

hyaluronic acid, injectable platelet rich fibrin

## **Primary outcome(s)**

1. Gingival thickness measured using a no.15 endodontic spreader (inserted perpendicularly from the vestibular midpoint 1.5 mm apical of the gingival margin through the soft tissue until a hard surface is reached, with a flowable composite used to mark the reference point) and a digital caliper to assess the penetration depth between the tip and the composite at baseline, 1, and 3 months
2. Keratinized tissue width measured from gingival margin to mucogingival junction with the help of a periodontal probe (UNC 15 probe) at baseline, 1, and 3 months

## **Key secondary outcome(s)**

1. Plaque index measured using a probe and a mirror to evaluate the plaque accumulation on the tooth at baseline, 1, and 3 months
2. Gingival index measured using a probe and a mirror to evaluate gingival inflammation at baseline, 1, and 3 months
3. Probing depth index measured using a periodontal probe to measure the periodontal pocket depth at baseline, 1, and 3 months
4. Clinical attachment loss (CAL) measured using a periodontal probe from the CEJ Cemento-enamel junction, to the gingival margin at baseline, 1, and 3 months
5. Bleeding on probing (BOP) measured on probing at baseline, 1, and 3 months

**Completion date**

10/01/2022

## Eligibility

**Key inclusion criteria**

1. Systemically healthy patients
2. Gingival thickness of the mandibular anterior teeth >1 mm
3. No pregnancy or lactation
4. Non-smokers

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

14

**Key exclusion criteria**

1. Active orthodontic treatment
2. Previous periodontal surgery
3. Use of any drug that might affect periodontal health
4. Malocclusion, crowding, missing or supernumerary teeth
5. Tooth mobility, bruxism

**Date of first enrolment**

01/04/2021

**Date of final enrolment**

01/08/2021

## Locations

**Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

Faculty of Dentistry

Department of Periodontology  
Mezzeh autostrade  
Damascus  
Syria  
20872

## Sponsor information

### Organisation

Damascus University

### ROR

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

## Funder(s)

### Funder type

University/education

### Funder Name

Damascus University

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

### IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/05/2022	18/08/2023	Yes	No