ISRCTN10040718 https://doi.org/10.1186/ISRCTN10040718

Modifying the characteristics of the gums using two different approaches

Submission date
05/07/2021

Recruitment status
No longer recruiting

Registration date
15/07/2021

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2020

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

Age group
Adult

Sex
Both

Target number of participants
21 patients

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
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

Website
http://www.justica.sp.gov.br/sites/SJDC/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan
Planned publication of results article.

Intention to publish date
01/11/2022

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?
Results article		18/05/2022	18/08/2023	Yes	No