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Testing a new treatment for receding gums

Submission date	Recruitment status	[_] Prospectively registered
01/05/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/05/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/07/2024	Oral Health	

Plain English summary of protocol

Background and study aims
Gingival recession (also known as receding gums) is when the gum tissue surrounding the teeth wears away or pulls back, exposing more of the tooth or its root. The aim of the study is to assess the effectiveness of an injectable blood extract with a gum graft during receding gums treatment.

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 will involve applying the gum graft alone on the diseased tooth, while the other will involves applying an injectable blood extract before applying a gum graft on it. Participants are followed up to measure gum recession at 1, 3 and 6 months.

What are the possible benefits and risks of participating?
The possible benefits of participating are achieving full coverage for receding gums sites, less 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 starting and how long is it expected to run for?
May 2020 to July 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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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
2400/S.M

Study information

Scientific Title
The efficiency of injectable platelet-rich fibrin (i-PRF) in root surface biomodification during gingival recession treatment

Study objectives
Injectable platelet-rich fibrin (i-PRF) with free gingival graft provides better root coverage compared to a free gingival graft alone during gingival recession treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/08/2020, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, Syria; +963 (0)1133923192; ap.srd@damascusuniversity.edu.sy), ref: 2400/S.M

Study design
Single-center interventional double-blinded randomized 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
Gingival recession

Interventions
Participants are randomised using a sealed envelope method. Two treatment methods will be compared, the first one will involve applying a free gingival graft alone on the root surface (control group), while the second will involve applying injectable platelet-rich fibrin (i-PRF) to a root surface before applying a free gingival graft (experimental group). Participants are followed up at 1, 3 and 6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Gingival recession depth measured using a UNC-15 probe at baseline, 1, 3, 6 months
2. Gingival recession width measured using a UNC-15 probe at baseline, 1, 3, 6 months

Secondary outcome measures
1. Probing depth measured using a UNC-15 probe at baseline, 1, 3, 6 months
2. Clinical attachment level measured using a UNC-15 probe at baseline, 1, 3, 6 months
3. Keratinized tissue height measured using a UNC-15 probe at baseline, 1, 3, 6 months
4. Healing measured using a healing index at 1, 2 weeks and 1 month after surgery
5. Pain measured using a visual analogue scale (VAS) at 1 week after surgery
6. Bleeding measured using a visual analogue scale (VAS) at 1 week after surgery
7. Dentine hypersensitivity measured using a visual analogue scale (VAS) at baseline, 1, 3, 6 months

Overall study start date
30/05/2020

Completion date
01/07/2022

Eligibility

Key inclusion criteria
1. ≥19 years of age
2. Periodontally and systemically healthy
3. Full-mouth plaque score (FMPS) and full-mouth bleeding score (FMBS) <15%
4. Presence of deep Miller Class I/II GR defect (≥3 mm in depth) at the buccal aspect of incisors and canines

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
42 sites (21 for each group)

Key exclusion criteria
1. Smoking
2. Contraindications for surgery
3. Presence of recession defects associated with caries, deep abrasion, restoration or pulpal pathology

Date of first enrolment
30/03/2021

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Periodontology
Faculty of Dentistry
Mezzah
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents (such as study protocol, statistical analysis plan etc) will be available.

Intention to publish date
01/07/2023

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 Tarik Kasem (prof.tarekkasem@hotmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/05/2023	09/07/2024	Yes	No