# Testing a new treatment for receding gums

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

#### 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? Dr Wajiha Albattal wajihaalbatal@gmail.com

## **Contact information**

Type(s)

Scientific

**Contact name** Dr Wajiha Albatal

ORCID ID https://orcid.org/0000-0002-0250-8380

**Contact details** Dummar Damascus Syria 00000 +963 (0)930429851 wajihaalbatal@gmail.com

## 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



#### 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 Damascus Syria 00000

## Sponsor information

**Organisation** Damascus University

Sponsor details

Albaramkeh Damascus Syria 00000 +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

## **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