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Root coverage with Emdogain versus root coverage with cross-linked hyaluronic acid

Submission date
20/11/2024

Recruitment status
No longer recruiting

Registration date
22/11/2024

Overall study status
Ongoing

Last Edited
12/09/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gingival recession, where the gum tissue recedes and exposes the tooth root, is a common dental condition that can lead to sensitivity, root decay, and aesthetic concerns. This study aims to compare two methods for treating gingival recession when combined with a connective tissue graft (CTG), the gold standard treatment. One method uses cross-linked hyaluronic acid (HA), and the other uses enamel matrix derivative (EMD). By comparing these treatments, the study hopes to identify which approach provides better gum coverage, tissue healing, and patient satisfaction.

Who can participate?
Adults aged 18 to 70 years old with specific types of gum recession (classified as RT1-2 or Miller Class I-III) in good general health can participate.

What does the study involve?
Participants will be randomly assigned to one of two treatment groups:
Group A: Connective tissue graft (CTG) combined with cross-linked hyaluronic acid (HA)
Group B: CTG combined with enamel matrix derivative (EMD)
A minimally invasive gum surgery will be performed in which the CTG will be placed into a tunnel created beneath the gums, and either HA or EMD will be applied to the tooth root. All procedures will be performed under local anesthesia by an experienced periodontist. The study includes follow-up visits to monitor healing and results for six months.

What are the possible benefits and risks of participating?
Participants may benefit from improved gum health, reduced sensitivity, and better aesthetics as part of their treatment. Risks are minimal and include common surgical risks such as swelling, mild discomfort, or temporary bleeding, all of which are manageable and expected to subside quickly.

Where is the study run from?
The Department of Periodontology, Victor Babes University of Medicine and Pharmacy, Timisoara, Romania

When Is the Study Starting and How Long Is It Expected to Run For?
November 2024 to December 2026, with recruitment, treatment, and follow-up taking place over 24 months. Results and analysis will be completed within 27 months.

Who is funding the study?
The University Clinic of Periodontology of Victor Babes University of Medicine and Pharmacy funds,

Who Is the Main Contact?
Dr. Meizi Eliezer, meizi.eliezer@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
ME/11.2024

Study information

Scientific Title
Root coverage with adjunctive enamel matrix derivative vs. cross-linked hyaluronic acid: 6-months, blinded RCT

Acronym
RC EMD XHYA

Study objectives
It is hypothesized that there is no significant difference in the primary outcomes of the percentage of root coverage and thickness of keratinized tissue between the crosslinked HA and EMD groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/11/2024, The Committee on Research Ethics of the Victor Babes University of Medicine and Pharmacy Timisoara (P-ța Eftimie Murgu, nr. 2, Timișoara, 300041, Romania; +40744521470; cecs@umft.ro), ref: 61/18.11.2024

Primary study design
Interventional

Study design
Single-blind randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gingival recession coverage treatment

Interventions
The study will include patients presenting with gingival recessions classified as RT1-2 (Cairo, 2011) or Miller Class I-III (Miller, 1985) on maxillary or mandibular teeth. A total of 60 recession defects will be enrolled and randomly allocated into two groups using block randomisation because it will ensure balanced group sizes at all stages of the trial. Group A will undergo recession coverage using a subepithelial connective tissue graft (CTG) combined with cross-linked hyaluronic acid (HA), while Group B will be treated with enamel matrix derivatives (EMD).

To ensure consistency, all surgeries will be performed under local anesthesia by a single experienced periodontist, Dr Meizi Eliezer. The surgical tunnel will be created using a lateral closed tunnel or a modified coronally advanced tunnel technique. The subepithelial CTG will be inserted into the tunnel, and either cross-linked HA or EMD will be applied to the exposed root surface to enhance regeneration and achieve optimal outcomes. Flaps will be repositioned and sutured. Patients will undergo standard post-operative care for regenerative procedures. Sutures will be removed three weeks after the surgery, and gentle brushing of the operated areas will be resumed after three weeks. Patients will enter supportive periodontal care, depending on the gingival and periodontal status.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Percentage of root coverage measured using a periodontal probe (PCP-UNC15 HuFriedy) with a consistent reference point (CEJ) measured to the gingival margin position at 6 months post-surgery

Key secondary outcome(s)
1. Clinical attachment level gain will be assessed through the following measures:
1.1. Probing depth measured using a periodontal probe (PCP-UNC15 HuFriedy) with a consistent reference point (CEJ) measured to the gingival margin position at 6 months post-surgery
1.2. Complete root coverage (CRC) measured using a clinical assessment of gingival margin position relative to the cementoenamel junction (CEJ) with periodontal probe (PCP-UNC15 HuFriedy), then CRC is calculated as the percentage of sites where full root coverage (no visible root exposure) has been achieved relative to the total number of sites treated, at 6 months post-surgery
2. Recession depth reduction will be assessed through the following measures:
2.1. Gingival thickness measured using a periodontal probe at 6 months post-surgery
2.2. Patient's perception measured using the Patient-Reported Outcome (PRO) Visual Analog Scale (VAS) immediately post-op (within 2-4 hours), Day 1 (24 hours post-surgery), Day 3 (72 hours post-surgery), Day 7 (1 week post-surgery) and at Day 14 and 1 month for delayed pain assessment
2.3 Esthetic outcomes measured using the Root Coverage Esthetic Score (RES) at the final 6-month visit

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Patients with RT1-2 or Miller 1-3, gingival recessions on maxillary or mandibular teeth
2. Aged between 18-70 years old
3. In good general health
4. Non-smokers or smoking up to 10 cigarettes/day

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit

70 Years

Sex
All

Total final enrolment
90

Key exclusion criteria
1. Systemic diseases affecting periodontal health
2. Without periodontal active disease
3. Smoking above 10 cigarettes/day
4. Pregnancy

Date of first enrolment
21/11/2024

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
Romania

Study participating centre
University Clinic of Periodontology, Victor Babes University of Medicine and Pharmacy Timisoara
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Sponsor information

Organisation
Victor Babeș University of Medicine and Pharmacy Timișoara

ROR
https://ror.org/00afdp487

Funder(s)

Funder type

University/education

Funder Name
Victor Babeș University of Medicine and Pharmacy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Dr. Meizi Eliezer, meizi.eliezer@gmail.com, and from Prof.Dr. Stefan-Ioan Stratul, s. stratul@gmail.com

IPD sharing plan summary
Available on request