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Periodontal infrabony defects treatment with bone grafts mixed with Emdogain vs. mixed with cross-linked hyaluronic acid

Submission date 22/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/10/2024	**Overall study status** Ongoing	
Last Edited 13/08/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Periodontal regeneration aims to restore the structure and function of the periodontal apparatus lost due to periodontal disease. Infrabony defects present a significant challenge in periodontal therapy. Current regenerative treatments for infrabony defects include bone substitutes mixed with biomaterials such as crosslinked hyaluronic acid (CLHA) or enamel matrix derivatives (EMD), each with unique properties and mechanisms of action. This study compares the clinical and radiological outcomes after treating infrabony defects with bone grafts mixed with CLHA or EMD.

Who can participate?
Patients aged 18-65 years old with periodontitis Stage II-IV and the presence of at least one infrabony defect of at least 4 mm in depth

What does the study involve?
This study compares two safe and approved ways of treating a specific type of bone defect in the gums. The treatments involve using bone grafts combined with either CLHA or EMD. These materials are commonly used in dental surgeries to help the gums and bones regenerate after damage caused by gum disease.

What are the possible benefits and risks of participating?
Both treatments have been tested and used successfully in many cases of gum disease. This study does not include experimental or untested procedures. Both treatments are safe and are regularly used by periodontists worldwide. The risks of participating are minor and are related to the usual risks of periodontal regenerative surgery: minor localized oedema, moderate gum recession, sometimes moderate tooth sensitivity.

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

When is the study starting and how long is it expected to run for?
October 2024 to December 2026

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

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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ME/2024

Study information

Scientific Title
Clinical outcomes after treatment of infrabony defects with bone grafts mixed with cross-linked hyaluronic acid or enamel matrix derivative: a 12-month randomized controlled trial

Study objectives
It is hypothesized that bone grafts mixed with cross-linked hyaluronic acid (CLHA) will demonstrate equivalent regenerative outcomes compared to enamel matrix derivatives in treating infrabony defects.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/10/2024, The Committee on Research Ethics of the Victor Babes University of Medicine and Pharmacy Timisoara (P-ta Eftimie Murgu nr. 2, Timisoara, 300041, Romania; +40744521470; cecs@umft.ro), ref: 51/21.10.2024

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgical regenerative treatment of infrabony periodontal defects

Interventions
In patients who completed steps 1 and 2 of periodontal therapy but failed to achieve the endpoints of therapy (no periodontal pockets >4 mm with bleeding on probing or no deep periodontal pockets ≥6 mm), the third (surgical) step of therapy will be performed. Infrabony defects will go through periodontal regeneration therapy. Under local anesthesia, full-thickness flaps will be raised to expose the infrabony defects. After debridement, Group A defects will be treated with bone grafts mixed with cross-linked hyaluronic acid (CLHA), while Group B defects the bone grafts will be mixed with EMD. Flaps will be repositioned and sutured. Patients will undergo standard post-operative care for regenerative procedures. Sutures will be removed 2 weeks after the surgery, and gentle brushing of the operated areas will be resumed after one more week. Patients will enter supportive periodontal care, depending on the gingival and periodontal status.

Block randomisation is used.

Intervention Type

Procedure/Surgery

Primary outcome(s)
Clinical attachment level (CAL) gain measured using calibrated periodontal probe (PCP-UNC15 HuFriedy)with a consistent reference point (CEJ) at 6- and 12-months post-surgery

Key secondary outcome(s))
1. Probing depth (PD) is measured using a calibrated manual periodontal probe with measurements taken at six sites per tooth at baseline, 6 months, and 12 months post-surgery
2. Reduction of BOP is measured using the calculated percentage of sites with BOP (BOP Percentage = Total number of sites probed / Number of sites with bleeding × 100) at baseline, 6 months, and 12 months post-surgery
3. Radiographic bone fill is measured using Linear Bone Fill Measurements at 6 months and 12 months post-surgery
4. Gingival recession is measured using direct clinical measurements with a periodontal probe from the CEJ to the free gingival margin at baseline, 6 months, and 12 months
5. Post-operative pain is measured using the Visual Analog Scale (VAS) at 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), Day 14, and 1 month for delayed pain assessment

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Patients aged 18-65 years with periodontitis Stage II-IV
2. Presence of at least one infrabony defect of at least 4mm in depth
3. No systemic conditions affecting periodontal healing
4. Non-smokers/smoking up to 8 cigarettes a day

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment

72

Key exclusion criteria
1. Horizontal defects
2. Pregnancy or lactation
3. Allergies to study materials
4. Smoking more than 10 cigarettes/ day

Date of first enrolment
23/10/2024

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 Babes University of Medicine and Pharmacy Timisoara

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 and from Prof. Dr Stefan-Ioan Stratul

IPD sharing plan summary
Available on request