

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

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<b>Registration date</b> 28/10/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/08/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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

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Public, Scientific, Principal investigator

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
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; ceacs@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  $\geq 6$  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

Bv. Revolutiei nr.9

Timișoara

Romania

300176

## 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