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Application of hyaluronic acid in the treatment of periodontitis (gum disease)

Submission date 11/03/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/03/2024	**Overall study status** Completed	
Last Edited 12/03/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Hyaluronic acid (HA) has been hypothesized to have influences on periodontal regeneration because it is an essential component of the periodontal ligament and has been shown to play various important roles. HA has an anti-inflammatory activity promoting soft and hard tissue healing.HA has already been tested in patients with chronic periodontitis in several clinical studies reporting the beneficial effects of HA. The present investigation aims to evaluate the clinical and radiological healing of vertical intrabony defects following surgical flap elevation and hyaluronic acid application compared to surgical flap elevation and enamel matrix proteins application.

Who can participate?
Patients suffering from periodontitis stage III, grades A and B.

What does the study involve?
Participants will be randomly allocated to receive surgical periodontal treatment either with the additional application of hyaluronic acid gel or with the additional application of enamel matrix proteins.

What are the possible benefits and risks of participating?
Participants will benefit from the periodontal surgical treatment. Hyaluronic acid products and enamel matrix derivates products have no reported risks.

Where is the study run from?
Department of Periodontology of the University of Medicine and Pharmacy " Victor Babes" Timisoara, Romani.

When is the study starting and how long is it expected to run for?
June 2019 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Vela Octavia Carolina, vela.octavia@umft.ro

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
11/ 20.05.2019

Study information

Scientific Title
Clinical and radiographic evaluation of intrabony periodontal defects treated with hyaluronic acid or enamel matrix proteins. A 6-month prospective study

Acronym
VBD-HIAL

Study objectives
The present investigation aims to evaluate the clinical and radiological healing of vertical intrabony defects following surgical flap elevation and hyaluronic acid application compared to surgical flap elevation and enamel matrix proteins application.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/05/2019, Scientific Research Ethics Committee of the University of Medicine and Pharmacy “Victor Babes” Timisoara (P-ta Eftimie Murgu, nr 2, Timisoara, 300041, Romania; +40256293389; comisiaeticaumft@umft.ro), ref: 11/ 20.05.2019

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Hospital, University/medical school/dental school

Study type(s)
Treatment, Efficacy

Participant information sheet
See outputs table

Health condition(s) or problem(s) studied
Surgical treatment of intrabony vertical defects in patients with Periodontitis stage III, grades A and B

Interventions
A randomized prospective 6-month, single-blind clinical, single-center, interventional study with a 1:1 allocation ratio according to computer-generated tables composed of two groups (test group: open flap debridement + hyaluronic acid application and control group: open flap debridement + enamel matrix proteins application), one surgeon will perform all surgeries using identical techniques, another specialist in periodontology, other than the surgeon will obtain the clinical and radiographical measurements.

The patients will be randomly assigned with a 1:1 ratio to one of the two groups through simple randomization, using a computerized random number generator(www.randomization.com). The allocation concealment will be performed using numbers associated with the test or control procedure. Even numbers will be associated with the test procedure, while odd numbers with the control procedure. The numbers on the cards will be enclosed in opaque envelopes. Treatment allocation will be performed at the time of surgery after debridement of the suprabony defects, by opening the envelope containing the number.

Test group (hyaluronic acid group): An access flap will be prepared after local anesthesia. Scaling and root planning will be performed by combining the use of metal curettes and power-driven instrumentation using an ultrasonic scaler. The hyaluronic acid gel (Hyadent) will be applied to

the exposed root surface respecting manufacturer indications, followed by a tension-free primary closure of the surgery wound using 6-0 monofilament (polypropylene) non-resorbable suturing material.

Control group (enamel matrix proteins (Emdogain) group): An access flap will be prepared after local anesthesia. Scaling and root planning will be performed by combining the use of metal curettes and power-driven instrumentation using an ultrasonic scaler. Enamel matrix proteins (Emdogain) will be applied to the exposed root surface respecting manufacturer indications, followed by a tension-free primary closure of the surgery wound using 6-0 monofilament (polypropylene) non-resorbable.

Follow up for 6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical attachment level (CAL) will be measured using periodontal probe at baseline and 6 months after the procedure

Secondary outcome measures
1. Probing Depth (PD) - measured using a periodontal probe at baseline and 6-month follow-up
2. Gingival Margin Level (GML) - measured using a periodontal probe at baseline and 6-month follow-up
3. Bleeding on Probing (BOP) - measured using a periodontal probe at baseline and 6-month follow-up
4. Full Mouth Bleeding Score (FMBS) - measured using a periodontal probe at baseline and 6-month follow-up
5. Full Mouth Plaque Score (FMPS) - measured using a periodontal probe at baseline and 6-month follow-up
6. Defect Depth (BC-BD) - measured on radiographs using radiographic imaging software at baseline and 6-month follow-up.
7. Defect Width (DW) - measured on radiographs using radiographic imaging software at baseline and 6-month follow-up.
8. Early Healing Index (EHI) - analyzed clinically 1 week after surgery

Overall study start date
20/05/2019

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. No systemic diseases that could influence the outcome of the therapy
2. Presence of 2-3 walls IBD ≥ 3 mm
3. An interproximal PD ≥ 6 mm
4. 6 weeks after subgingival instrumentation at the experimental sites
5. Good oral hygiene
6. Non-smokers

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
40

Total final enrolment
60

Key exclusion criteria
1. Patients with systemic diseases known to affect the outcome of periodontal therapy
2. Immunocompromised individuals
3. Pregnant or lactating females
4. Tobacco smokers or tobacco use in any form
5. Non-compliant patients
6. Prolonged antibiotic treatment or anti-inflammatory treatment within 6 months prior the surgery
7. Grade C periodontitis
8. Furcation involvement at the same tooth
9. Mobility grade II/III
10. Poor oral hygiene
11. Patients with parafunctional habits
12. Patients who had periodontal surgery in the last 6 months
13. Orthodontic treatment during the previous year
14. Occlusion trauma
15. Interproximal open contact points
16. One-walled or combined one- and two-walled defects confirmed upon surgical exposure

Date of first enrolment
01/06/2019

Date of final enrolment
01/06/2023

Locations

Countries of recruitment

Romania

Study participating centre
Faculty of Dental Medicine, Victor Babes University of Medicine and Pharmacy
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Sponsor information

Organisation
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University/education

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request(Dr Vela Octavia Carolina vela.octavia@umft.ro)
Type of data: periodontal charts.
Data will become available after publication of the study, and will be available for 5 years.
Data will be shared for similar studies, on request from the first author.
Written consent from participants will be obtained.
Data from participants are anonymized. The key to the names of the participants is located in the repository

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Romanian		12/03/2024	No	Yes