

STUDY PROTOCOL

Diode Laser-Assisted Periodontal Therapy in Kidney Transplant Recipients

Official Title	Diode Laser-Assisted Periodontal Therapy in Kidney Transplant Recipients
Unique Protocol ID	MH103-KTR-PERIOLASER-RCT-2026
NCT Number	NCT number not yet assigned
Protocol Version	Version 1.0
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Sponsor / Responsible Institution	Military Hospital 103 / Vietnam Military Medical University
Study Setting	Military Hospital 103, Hanoi, Vietnam

1. Protocol Synopsis

Item	Description
Study design	Single-center study with two components: (1) a cross-sectional assessment of periodontal status in kidney transplant recipients and (2) a randomized controlled, parallel-group clinical trial in transplant recipients with mild-to-moderate periodontitis.
Population	Adult kidney transplant recipients followed at Military Hospital 103; intervention phase limited to those with mild-to-moderate periodontitis and at least one functional sextant.
Planned sample size	80 participants total (40 per group), allowing for attrition from the minimum calculated sample size of 36 per group.
Study arms	Arm A: scaling and root planing (SRP) plus adjunctive diode laser therapy. Arm B: SRP alone.
Follow-up	Baseline, 1 month, 3 months, and 6 months after treatment.
Main periodontal variables	Plaque Index (PII), Gingival Index (GI), Bleeding on Probing (BOP), Probing Depth (PD/PPD), Clinical Attachment Loss (CAL), Oral Hygiene Index-Simplified (OHI-S), and radiographic bone status.
Laboratory / ancillary variables	Blood tests (including CRP, urea, creatinine, and hematologic parameters), radiographs, and subgingival microbiological analysis using 16S rRNA-based sequencing according to the proposal.

Item	Description
Study duration	December 2025 to June 2026

2. Background and Rationale

Periodontitis is a chronic inflammatory condition initiated by dysbiotic dental biofilm and characterized by destruction of the supporting tissues of the teeth. Kidney transplant recipients may be particularly vulnerable because of long-term immunosuppression, altered host defense, and frequent coexisting metabolic disorders. The uploaded proposal states that no Vietnamese study has systematically described periodontal status in kidney transplant recipients while also evaluating adjunctive diode laser therapy in this population. The study therefore combines an epidemiologic phase with a randomized treatment phase to address both disease burden and treatment response.

Adjunctive diode laser therapy is expected to improve decontamination of periodontal pockets, reduce inflammation and bleeding, and support soft-tissue healing when added to standard non-surgical periodontal treatment.

3. Objectives

To evaluate the effectiveness of adjunctive diode laser therapy combined with SRP compared with SRP alone in kidney transplant recipients with periodontitis.

Secondary objectives include describing radiographic and microbiological characteristics, exploring changes in selected laboratory biomarkers, and identifying factors associated with treatment response.

4. Study Setting and Timeline

This study will be conducted at the Department/Unit of Odonto-Stomatology and the transplant follow-up services of Military Hospital 103, Vietnam Military Medical University, Hanoi, Vietnam.

Planned study period: December 2025 through June 2026.

5. Study Design

- This public study protocol describes the randomized, controlled, parallel-group interventional component only. Eligible kidney transplant recipients with mild-to-moderate periodontitis will be assigned to one of two treatment arms.
- The trial is single-center. This operational method should be confirmed against the final approved randomization procedure before public posting.

6. Participant Selection

6.1 Inclusion Criteria

- Diagnosed with end-stage kidney disease and previously treated with kidney transplantation.
- Followed after kidney transplantation at Military Hospital 103.
- At least 6 months post-transplant at the time of enrollment.
- Able and willing to participate and provide written informed consent.
- For the intervention phase: diagnosis of mild-to-moderate periodontitis, at least one functional sextant, and ability to complete periodontal treatment and follow-up.

- No periodontal treatment or systemic antibiotic therapy within 6 weeks before sample collection for the interventional component.

6.2 Exclusion Criteria

- Severe systemic disease judged by investigators to interfere with participation or interpretation of outcomes.
- Severe periodontitis as operationally excluded in the proposal (including PD \geq 7 mm and CAL \geq 5 mm).
- Previous recent treatment with diode laser or periodontal surgery within 6 weeks before enrollment.
- Edentulous patients.
- Inability to adhere to scheduled follow-up visits.
- Refusal to participate.

7. Enrollment, Allocation, and Study Arms

Eligible participants for the interventional phase will be assigned to one of two groups after baseline examination.

Arm	Intervention	Details
Arm A	SRP + diode laser	Supragingival scaling, subgingival debridement/root planing, oral hygiene instruction, maintenance care, and adjunctive 810-nm diode laser therapy.
Arm B	SRP alone	Supragingival scaling, subgingival debridement/root planing, oral hygiene instruction, and maintenance care without diode laser therapy.

8. Interventions

Standard periodontal therapy will include oral hygiene instruction, supragingival scaling, subgingival debridement, and root planing using routine periodontal instruments and ultrasonic devices, followed by maintenance care.

The protocol proposal specifies use of an 810-nm diode laser as adjunctive therapy in the intervention arm. Device-specific settings and operating steps should match the final IRB-approved version and institutional device SOP before upload.

The proposal also references repeat follow-up and maintenance visits; any concomitant mouthrinse or antibiotic regimen should be aligned with the final approved treatment manual and listed consistently across public and internal versions.

9. Study Procedures and Assessments

Assessment	Baseline	1 month	3 months	6 months
Eligibility / consent	X			
Medical and transplant history	X			

Assessment	Baseline	1 month	3 months	6 months
Periodontal examination (PII, GI, BOP, PD, CAL, OHI-S)	X	X	X	X
Tooth mobility / clinical oral exam	X	X	X	X
Radiographic assessment	X			X
Blood tests (hematology / biochemistry incl. CRP, urea, creatinine)	X	X	X	X
Subgingival microbiology / 16S rRNA sequencing	X	X		
Periodontal treatment / maintenance	X	X	X	X

10. Outcome Measures

- Change in periodontal probing depth from baseline to follow-up visits.
- Change in clinical attachment loss from baseline to follow-up visits.
- Change in gingival inflammation and bleeding parameters (GI and BOP).
- Changes in plaque control and oral hygiene indices (PII and OHI-S).
- Radiographic change in alveolar bone status.
- Changes in selected laboratory biomarkers, including CRP and renal-function-related markers.
- Change in subgingival microbial profile based on molecular testing.

11. Sample Size

For the interventional phase, the proposal uses a two-group comparison with $p_1 = 0.50$, $p_2 = 0.75$, $\alpha = 0.05$, and $\beta = 0.20$, yielding 36 participants per group. The planned operational sample is 40 participants per group (80 total).

12. Statistical Analysis Plan (integrated summary)

Descriptive statistics will summarize demographic, transplant-related, clinical, radiographic, laboratory, and microbiological variables.

Compare changes over time within groups and between groups using statistical tests appropriate to variable type and distribution. Repeated-measures approaches may be used for longitudinal outcomes as defined in the final analysis plan.

All statistical testing will be two-sided with a nominal significance threshold of 0.05 unless otherwise specified in the final approved SAP.

13. Safety Monitoring and Adverse Events

This study involves non-surgical periodontal treatment and adjunctive diode laser therapy, both of which may cause transient discomfort, tooth sensitivity, mild bleeding, or soft-tissue irritation.

Participants will be observed during and after procedures, and clinically important adverse events will be documented and managed according to institutional practice. Kidney transplant recipients will continue routine transplant follow-up and immunosuppressive management through their treating physicians.

Any serious or unexpected event will be reported according to institutional ethics requirements and local regulations.

14. Data Collection, Confidentiality, and Quality Control

Study data will be recorded on study forms and in secure research files using coded identifiers. No participant names should appear in any public document uploaded to ClinicalTrials.gov.

Only authorized research personnel will have access to identifiable information. Public-facing documents will contain no directly identifying participant information.

Clinical measurements should be performed using standardized periodontal methods and calibrated examiners whenever applicable.

15. Ethics

The study was approved by Ethics Committee in Biomedical Research, Vietnam Military Medical University (Approval No. 119/CNChT-HĐĐĐ). Written informed consent will be obtained from all participants before any study-specific procedures.

16. Publication and Public Posting

This protocol is intended for public posting as a study document. Public and internal versions should remain materially consistent regarding objectives, design, eligibility, interventions, and outcome measures.

Any later substantive amendment should be reflected in both the local master protocol and the public document version as appropriate.