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The role of diode laser in the management of periodontitis among hemodialysis patients

Submission date 04/08/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/08/2024	**Overall study status** Completed	
Last Edited 12/08/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims

The kidney is considered one of the important organs in maintaining the human body's normal functions, and any disturbance in its function negatively affects general health. Therefore, to avoid any dangerous complications among chronic kidney disease patients, hemodialysis is used to replace normal kidney function.

Oral tissues may also be affected by the disease, especially in its final stages and by the medication and hemodialysis process.

Periodontal (gum) disease is considered one of the most important manifestations associated with kidney disease. If left untreated, it may cause teeth loss and halitosis (bad breath) and increase the systemic inflammatory burden in the body. It is usually treated by scaling and root planing.

Recently, the application of dental lasers such as diode or Nd:YAG could improve the healing process and support periodontal tissues, which might be due to the laser's thermal antibacterial effects on oral tissues. The aim of this study is to assess the effect of diode laser as an adjacent treatment to scaling and root planing on oral and periodontal health among hemodialysis patients.

Who can participate?

Patients aged 20-50 years with chronic kidney disease undergoing hemodialysis.

What does this study involve?

Participants are randomly allocated to the two treatment methods: traditional scaling and root planing (SRP), and SRP + diode laser application. Oral health and hygiene instructions are provided for all patients.

What are the possible benefits and risks of participating?

Benefits may include periodontal health improvement, preventing tooth loss, and reduced inflammation. Patients will be more aware of their oral health and its importance for their quality of life. Possible risks might include some pain and discomfort after the laser application.

Where is the study run from?

Damascus University (Syria)

When is the study starting and how long is it expected to run for?
August 2021 to September 2023

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Samer AlTarsha, samer.altarsha@damascusuniversity.edu.sy

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
164

Study information

Scientific Title
Diode laser as an adjacent treatment to scaling and root planing – oral and periodontal health among hemodialysis patients – a randomized single-blinded clinical trial

Study objectives
h0: There are no statistical differences between both treatment groups (SRP vs SRP and diode laser) regarding the clinical studies indices.
h1: There are statistically significant differences between both treatment groups (SRP vs SRP and diode laser) regarding the clinical studies indices.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 27/09/2021, Scientific ethics committee at Damascus University. (Baramkeh, Damascus, 4671, Syria; +963 (0)1133923223; ap.srd@damascusuniversity.edu.sy), ref: 3398

Study design
Single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Periodontal disease among hemodialysis patients

Interventions
This study is designed to compare traditional non-surgical treatment (scaling and root planing), and scaling and root planing with the use of diode laser 810 nm. This is a split-mouth design study in which both treatment groups were randomly selected for each half of the jaws for every patient.

Intervention Type
Mixed

Primary outcome(s)
Relative attachment level (RAL), defined as the distance from the highest point of the teeth (incisal edge in anterior teeth and occlusal edge in posterior teeth) to the bottom of the periodontal pocket. It approximately measures bone loss due to periodontal disease. Measured using a periodontal probe (UNC15) at baseline and after a 3-month follow-up appointment.

Key secondary outcome(s))
1. Periodontal probing depth (PPD), defined as the distance from the free gingival margin to the bottom of the periodontal pocket. Measured using a periodontal probe (UNC15) at baseline and after a 3-month follow-up appointment.
2. Level of oral hygiene and periodontal health measured using the Simplified Oral Hygiene Index (SOHI) at baseline and after a 3-month follow-up appointment.

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Chronic kidney disease patients
2. Patients undergoing hemodialysis twice a week
3. Patients with more than eight teeth in each half of their oral cavity
4. Aged 20-50 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
50 years

Sex
All

Total final enrolment
33

Key exclusion criteria
1. Pregnancy
2. Diabetes patients
3. Patients who underwent an antibiotic therapy course in the last 6 months
4. Patients who underwent periodontal treatment in the last 6 months
5. Chemotherapy patients

Date of first enrolment
10/05/2022

Date of final enrolment
20/08/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Faculty of Dental Medicine
Oral Medicine Department
Mazzeh Highway
Damscus
Syria
4671

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study are available upon request from Samer AlTarsha (sameraltarsha@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			07/08/2024	No	No
Participant information sheet			07/08/2024	No	Yes