

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

Submission date 04/08/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/08/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name
Dr Samer AlTarsha

Contact details
Hamish Highway
Damascus
Syria
4671
+963 (0)932759493
samer.altarsha@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
164

Study information

Scientific Title
Diode laser as an adjunct 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Prevention, Treatment

Participant information sheet

See study outputs table

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/08/2021

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

Age group

Adult

Lower age limit

20 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

30

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

Mazzeah Highway

Damascus

Syria

4671

Sponsor information**Organisation**

Damascus University

Sponsor details

Baramkeh

Damascus

Syria

4671

+963 (0)1133923223

ap.srd@damascusuniversity.edu.sy

Sponsor type

University/education

Website

<http://www.damascusuniversity.edu.sy>

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/09/2024

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