

The affect of diode laser on healing after dental extraction in patients diabetes mellitus

Submission date 14/02/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/02/2025	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

Patients visiting dental clinics and those suffering from type 2 diabetes often experience vascular fragility, subsequent bleeding, delayed healing, and the need for various diluents. Therefore, it is essential to develop special materials for these patients that reduce bleeding, accelerate healing, and minimize infections, making extraction safe, easy, and comfortable for both the doctor and the patient. One of these materials is a diode laser, which has numerous positive effects on the body, including pain relief, reduced bleeding, and the promotion of growth factors, thereby enhancing healing.

Who can participate?

Patients aged 35 years and older with Type II Diabetes require symmetrical tooth extraction.

What does the study involve?

The control group will receive a placebo laser after the tooth while the experimental group will receive a diode laser after tooth extraction. The participants will be followed up for 7 days.

What are the possible benefits and risks of participating?

The potential benefits of using lasers for diabetics include pain relief, bleeding, and expedited healing. However, the potential risks involve prolonged working time and Contraindications in cases of local infection.

Where is the study run from?

Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University (Syria)

When is the study starting and how long is it expected to run for?

November 2022 to January 2025

Who is the funding of the study?

Investigator initiated and funded

Who is the main contact?

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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

Nil known

Study information

Scientific Title

The affect of diode laser on healing after dental extraction in patients type 2 diabetes mellitus

Study objectives

The null hypothesis posited that there is a significant difference between a diode laser and a placebo laser in enhancing healing after tooth extractions in individuals with type 2 diabetes mellitus.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 26/11/2024, Damascus University (Oral and Maxillofacial Surgery Department - Faculty of Dental Medicine) (Mezzeh Highway, Damascus, -, Syria; +963 1133923192; ap.srd@damascusuniversity.edu.sy), ref: DN-261124-351

Study design

Double-blind randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Improving healing after dental extraction in individuals with diabetes

Interventions

This study is a randomized controlled trial, involving the application of a diode laser and a placebo laser. The control group will receive a placebo laser after the tooth while the experimental group will receive a diode laser after tooth extraction. The diode and placebo lasers will be randomized into two groups using <http://www.randomizer.org/>. The follow-up period for each patient is one week, with visits:

1) 2 days postoperative and 2) 7 days postoperative.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Wound healing will be measured at three endpoints: T0 immediately after laser application, T1 at 2 days, and T2 at 7 days by Landry Gingival healing index

Key secondary outcome(s)

Pain will be assessed using a visual analog scale and the painkiller pills at T0 immediately after laser application, T1 at 2 days, and T2 at 7 days

Completion date

15/01/2025

Eligibility

Key inclusion criteria

1. Patients with Type 2 diabetes and HbA1c levels between 8-10%.
2. Individuals over 35 years of age.
3. Patients classified as ASA type II – III.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

35 years

Upper age limit

70 years

Sex

All

Total final enrolment

20

Key exclusion criteria

1. HbA1c less than 8 or greater than 10.
2. Antibiotic or NSAID use 1- days before extraction.
3. Smoking more than 10 cigarettes a day.
4. Local infection at the site of the tooth to be extracted.

Date of first enrolment

12/01/2024

Date of final enrolment

05/01/2025

Locations

Countries of recruitment

Syria

Study participating centre

Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University

Mezzeh Highway

Damascus

Syria

4671

Sponsor information

Organisation

Damascus University

ROR

<https://ror.org/03m098d13>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

the data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date