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

Submission date 14/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/02/2025	**Overall study status** Completed	
Last Edited 20/02/2025	**Condition category** Oral Health	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
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

Overall study start date
01/11/2022

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

Age group
Adult

Lower age limit
35 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
15

Total final enrolment
20

Key exclusion criteria
1. HbA1c less than 8 or greater than 10.
2. Antibiotic or NSAID use1- 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
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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http://www.damascusuniversity.edu.sy

ROR
https://ror.org/03m098d13

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

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