# How low-level laser therapy helps dental implants stay stable in different bone types

Submission date 17/03/2025	<b>Recruitment status</b> Recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
Registration date 19/03/2025	<b>Overall study status</b> Ongoing	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 17/06/2025	<b>Condition category</b> Oral Health	<ul> <li>Individual participant data</li> <li>[X] Record updated in last year</li> </ul>

#### Plain English summary of protocol

#### Background and study aims

The purpose of this study is to evaluate the effectiveness of laser biomodulation in enhancing the osseointegration and stability of dental implants. This research aims to improve the outcomes of dental implant procedures, potentially offering better long term success rates for patients and shortening the loading time.

Who can participate?

Patients aged 18-60 years old who are medically fit with sufficient bone volume and require bilateral maxillary dental implants.

#### What does the study involve?

Participants in this study will undergo the standard dental implant procedure with the application of laser every 2 weeks for 2 months. The procedure will be performed by a qualified dental professional, and follow-up visits will be scheduled to monitor the osseointegration and stability of the implant. During these visits, they may undergo radiographic imaging and other assessments as required.

What are the possible benefits and risks of participating?

Participants may benefit from improved implant outcomes. However, these benefits are not guaranteed. The risks involved in this study are similar to those associated with standard dental implant procedures, including but not limited to infection, implant failure, and discomfort. In addition, the use of laser is expected to enhance implant stability and osseointegration, potentially reducing the risk of implant failure.

#### Where is the study run from?

The study will be conducted at the postgraduate clinics of the College of Dentistry, University of Sulaimani.

When is the study starting and how long is it expected to run for? December 2024 to November 2025 Who is funding the study? Investigator initiated and funded

Who is the main contact? Omer Ali Hama, Omer.hama@univsul.edu.iq

## **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 Research ID (702), College of Dentistry/ University of Sulaimani

# Study information

#### Scientific Title

Effect of low-level laser therapy on stability of dental implants in D3 and D4 bone quality: a splitmouth randomized controlled clinical trial

#### **Study objectives**

Regarding secondary implant stability after 2 months, there is no significant difference between using laser therapy on the implant area and following standard procedures for dental implants in D3 and D4 bone quality in the upper jaw.

#### Ethics approval required

Ethics approval required

**Ethics approval(s)** Approved 16/12/2024, The Ethics Committee of the College of Dentistry (University of Sulaimani, As Sulaymaniyah, 46001, Iraq; +964 770 452 2890; dentistry.ethics@univsul.edu.iq), ref: COD-EC-24 -0057

**Study design** Split-mouth randomized controlled trial

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** Dental clinic, University/medical school/dental school

**Study type(s)** Efficacy

Participant information sheet

See study outputs table

#### Health condition(s) or problem(s) studied

Effect of low-level laser therapy on stability of dental implants in D3 and D4 bone quality

#### Interventions

Sample and sample size

Forty implants in patients aged 18-60 years old, requesting dental implants with bilateral D3 and D4 maxillary bone after taking informed consent for participation in this study will be included in this study. Then patients will be randomly recruited and the maxillary arches will be randomly assigned to two groups (20 implants for each group). For the randomization when a patient is recruited before any radiographic or clinical assessment randomly we assign one side of the Jaw to be study group and the other side as the control. This commenced with the upper right side being the control in the first case, the left side being the control in the next case and so on.

First group: Standard implant site preparation. (Control group one side of the maxilla for each test group).

Second group: Standard implant site preparation and Laser photobiomodulation. Exclusion Criteria: Patients with systemic disease that affects bone metabolism and healing, smokers and bone height less than 10 mm will be excluded.

Cone-beam computed tomography (CBCT) radiological assessment is going to be done for each patient to determine the volume of bone and density using the Hounsfield unit (HU).
Surgical guide and flapless approach will be used for placement of the implants and for the precise localization of the implant for the next visits.

- PSK line two piece Oxy dental implants, diameter of 4.0 mm and 4.5 mm and length of 10.0 mm and 11.5 mm will be placed in at least 10 patients.

- Delayed implant placement and delayed loading protocols will be employed in this study.

- Low Level Diode laser will be used for laser group and the first session will be applied on the first day of implant placement and will continue over 2 months at intervals of every 2 weeks.
- Lasing Parameters: Wavelength (940nm) at a 2mm distance, continuous wave with 0.3 W output power at four different locations (Buccal, Palatal, Mesial and Distal) for 20 seconds each at minimum 10 J/cm2.

- Resonance Frequency Analysis (RFA) using Osstell® device will be used to record the ISQ at time of implant placement and after 2 months.

The Osstell ISQ Scale will be used to define the stability of the implant.

#### Intervention Type

Procedure/Surgery

#### Primary outcome measure

Implant stability quotient (ISQ) value measured using Resonance Frequency Analysis with an Osstell® device at time of implant placement and after 2 months

#### Secondary outcome measures

Marginal bone loss measured using cone-beam computed tomography (CBCT) radiological assessment in the initial healing period

**Overall study start date** 01/12/2024

**Completion date** 01/11/2025

# Eligibility

**Key inclusion criteria** Medically fit patients requesting bilateral dental implants with D3 and D4 maxillary bone

Participant type(s) Patient

**Age group** Adult

**Lower age limit** 18 Years

**Upper age limit** 60 Years

**Sex** Both

**Target number of participants** 10

#### Key exclusion criteria

 Patients with systemic diseases and/or on medications that affect bone metabolism and healing
 Smokers
 Bone height less than 10 mm

Date of first enrolment 01/12/2024

Date of final enrolment 01/09/2025

### Locations

Countries of recruitment Iraq

**Study participating centre College of Dentistry, University of Sulaimani** City campus, Eskan, Zanko Street, Sulaimania As sulaymaniyah Iraq 46001

## Sponsor information

**Organisation** University of Sulaimani

#### Sponsor details

City campus, Eskan, Zanko Street, Sulaimania Sulaymaniyah Iraq 46001 +9647725447528 pg.dent@univsul.edu.iq

**Sponsor type** University/education

Website https://univsul.edu.iq

ROR https://ror.org/00saanr69

# Funder(s)

**Funder type** Other

**Funder Name** Investigator initiated and funded

## **Results and Publications**

#### Publication and dissemination plan

Planned publication in a peer-reviewed journal

#### Intention to publish date

01/02/2026

#### 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

Study outputs							
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?		
Participant information sheet			19/03/2025	No	Yes		