Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Low-Level Laser Therapy on Osseointegration of Posterior Dental Implants: A Randomized, Double-Blind, Split-Mouth Clinical Trial

Protocol summary

Study aim
Examining the effect of low level laser therapy on osseointegration of posterior implants

Design
Randomized, double-blind, split-mouth clinical trial, on 17 patients (34 implants). Randomization is performed using a computer-generated random number sequence

Settings and conduct
The study is conducted at the clinic of Mashhad School of Dentistry. Patients requiring bilateral implants in the premolar and molar regions of the mandible are selected. One side is considered as the test group and the opposite side as the control group. Patients and evaluators are blinded to the grouping. Implant stability measurements are performed using the Ostell device in four sessions

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Patients should have sufficient bone volume for implant placement without GBR (Guided Bone Regeneration). - Patients should have signed an informed consent form. - The target bone should be type D3 or D4. - Patient cooperation should be excellent. Exclusion criteria:1. Patients with insufficient bone volume requiring GBR 2. Bone type D1 or D2 3. Need for implants in areas other than mandibular premolars and molars4. Need for implants only on one side of the mandible (inability to perform split-mouth design)5. Systemic diseases affecting bone healing process6. Use of medications affecting bone metabolism7. History of radiotherapy in the head and neck region

Intervention groups
Intervention group: Low-level laser therapy (LLLT) with 940 nm wavelength, 100 mW output power, in continuous mode, for 40 seconds from buccal and lingual sides, on days 2, 4, 6, 8, 10, and 12 post-surgery. Control group: Same protocol with the laser device turned off

Main outcome variables
Implant stability measured by Ostell device on days 0, 10, 21, and 42 post-surgery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240721062500N1**
Registration date: **2024-08-25, 1403/06/04**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-25, 1403/06/04**
Update count: **0**

Registration date
2024-08-25, 1403/06/04

Registrant information
Name
Negar Asgarianomran
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 4329 4105
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-07-22, 1403/05/01
Expected recruitment end date
2025-01-20, 1403/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Effect of Low-Level Laser Therapy on Osseointegration of Posterior Dental Implants: A Randomized, Double-Blind, Split-Mouth Clinical Trial

Public title

the effects of low level laser therapy on osteointegration on posterior implants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should have sufficient bone volume for implant placement without GBR (Guided Bone Regeneration) Patients should have signed an informed consent form The target bone should be type D3 or D4. Patient cooperation should be excellent

Exclusion criteria:

Patients with insufficient bone volume requiring GBR Bone type D1 or D2 Need for implants in areas other than mandibular premolars and molars Need for implants only on one side of the mandible (inability to perform split-mouth design) Systemic diseases affecting bone healing process Use of medications affecting bone metabolism History of radiotherapy in the head and neck region

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **17**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patients who need to place implants in the mandibular premolar and molar region on two sides will be selected. One side will be used as a test and the opposite side will be used as a control. (split mouth)

Randomization (investigator's opinion)

Randomized

Randomization description

This study will use a simple randomization method with a split-mouth design. The randomization process will be as follows: - Randomization unit: Individual patient's mouth sides (right vs left) - Randomization tool: Computer-generated random number sequence - Sequence generation: A statistician not involved in the study will generate a random sequence using statistical software (e.g., R or SAS) - Allocation concealment: Opaque, sealed envelopes will be used. Each envelope will contain the allocation for the right side of the mouth (laser or control), with the left side automatically assigned to the opposite group. - Implementation: After the patient is deemed eligible and has signed the informed consent, the treating clinician will open the envelope to determine which side receives the laser treatment. The split-mouth design ensures that each patient serves as their own control, reducing inter-individual variability.(1. A statistician outside the research team generates a random list of 0s and 1s, equal to the number of patients, using R software (version 4.1.2). The number 0 indicates laser allocation to the right side, and 1 indicates laser allocation to the left side. 2. This random list is placed in opaque, sealed envelopes. Each envelope is marked with a serial number corresponding to the patient's entry number into the study. 3. After confirming the patient's eligibility and signing the informed consent form, the research assistant (who is not involved in the treatment process) opens the envelope for that patient and informs the surgeon of the allocation. 4. Based on this allocation, the surgeon performs the laser treatment on the specified side. The opposite side is automatically assigned to the control group. 5. Each patient's allocation is recorded on a separate form accessible only to the research assistant and the surgeon. This method ensures that the allocation is completely random and cannot be predicted or manipulated.)

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a randomized, double-blind clinical trial: 1. Patients (Participants): Patients are blinded to which side of their mouth is receiving laser treatment and which side is the control group. They do not know in which sessions the laser is active and in which it is turned off. 2. Evaluators: The individuals responsible for measuring implant stability using the Ostell device are blinded to which side has received laser treatment and which is the control group. They simply perform the measurements without knowledge of the implant grouping. The principal investigator and the treatment team applying the laser cannot be blinded as they need to know which side to treat with the active laser and which with the inactive laser. Statistical analysts can also be kept blinded by providing them with coded data without specifying the groups. This type of blinding helps reduce bias in the evaluation of results, as neither patients nor evaluators are aware of the grouping. Additionally, the use of an inactive laser in the control group (instead of not using the device at all) helps maintain patient blinding, as they cannot discern whether they have received actual laser treatment or not. The main researcher and the treatment team applying the laser cannot be blinded, as they need to know which side to treat with the active laser and which with the inactive one. Statistical analysts can also be kept blinded by providing them with coded data without specifying the groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Khorasan Razavi, Mashhad, In front of Mellat Park - Faculty of Dentistry

City
mashhad

Province
Razavi Khorasan

Postal code
9177899191

Approval date
2024-06-08, 1403/03/19

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1403.084

Health conditions studied

1

Description of health condition studied
Osseointegration of posterior implants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Implant stability measured by Ostell device on days 0, 10, 21, and 42 post-surgery

Timepoint
On days 0, 10, 21, and 42 post-surgery

Method of measurement
Implant stability measured by Ostell device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Low-level laser therapy (LLLT) with 940 nm wavelength, 100 mW output power, in continuous mode, for 40 seconds from buccal and lingual sides, on days 2, 4, 6, 8, 10, and 12 post-surgery

Category
Placebo

2

Description
Control group: Low power off laser (LLLT), in continuous mode, for 40 seconds from the buccal and lingual side, on days 2, 4, 6, 8, 10 and 12 after surgery.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic of Mashhad Faculty of Dentistry

Full name of responsible person
Amir Moeintaghavi

Street address
Faculty of Dentistry, Vakilabad Blvd, Mashhad , Iran

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Province
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MoeentaghaviA@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Rasool Saheb Alam

Street address
Faculty of Dentistry, Vakilabad Blvd, Mashhad , Iran

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mvzynb@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Negar Asgarianomran
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identification of individuals.
When the data will become available and for how long
The access period begins immediately after the publication of results.
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions. Those working in industry can also apply to receive the data.
Under which criteria data/document could be used
The data and documents from this study are to be used solely for research purposes and in compliance with confidentiality principles. Access to the data is permitted only for the research team, and any publication of results will be without mentioning patients' personal information.
From where data/document is obtainable

To obtain data or documents related to this study, please contact the principal investigator, Dr. [Negar Asgarian], via email :Asgariann4001@mums.ac.ir . Requests will be addressed after review and approval by the university's research ethics committee.

What processes are involved for a request to access data/document

Submit a written request to the principal investigator Review of the request by the research team Evaluation and approval of the request by the research ethics committee If approved, signing of a confidentiality agreement by the requester Provision of data or documents in coded form without patients' personal information This process typically takes 2 to 4 weeks.

Comments