

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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Iran (Islamic Republic of)

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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

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Sponsors / Funding sources

1

Sponsor

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Mashhad University of Medical Sciences

Full name of responsible person

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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

Dentistry

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Full name of responsible person

Negar Asgarianomran

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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