

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of 810 nanometer (nm) low level diode laser irradiation on dental implant stability in posterior mandibular region .

Protocol summary

Study aim

Aim of this study was to assess the low level laser effect on implants stability.

Design

Randomised, superiority, parallel group trial with blinded outcome assessment.

Settings and conduct

the selected patients were then were placed implants. The test and control group were matched in terms number, diameter and length of implants. all implants had almost similar torque, then were prescribe protocol postoperative. After the surgery, one of the sides of the lower jaw of the patients was randomly (computer-generated random numbers) chosen to receive low level laser treatment (test group) and then repeated 4 other time. The other side of the jaw was placebo, inactive treatment performed and served as a control (control group). stability all implants were measured within 6 week. the cases are done at Faculty of Dentistry; Ahvaz Jundishapur University of Medical Sciences.

Participants/Inclusion and exclusion criteria

The inclusion criteria were follows: 1) Need for posterior implant on the mandibular sides 2) Sufficient bone volume to receive implant without requiring bone augmentation (reconstruction) procedure in subject area
The exclusion criteria were: 1) Pregnancy 2) Smoking habits 3) History of previous tooth extraction in the last six months in the selected area 4) System disease that effects osseointegration 5) Anticoagulant therapy 6) Systemic glucocorticoid therapy 7) History of radiotherapy in the craniofacial region 8) Acute infection in the mouth, uncontrolled or untreated periodontal disease 9) Patients without good oral hygiene

Intervention groups

following the split-mouth design, implants were inserted in the posterior mandible of 8 patients. one mandible side randomly received low level laser therapy (test group), while the other side was placebo (control group)

Main outcome variables

Implant stability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180407039212N1**

Registration date: **2018-05-16, 1397/02/26**

Registration timing: **retrospective**

Last update: **2018-05-16, 1397/02/26**

Update count: **0**

Registration date

2018-05-16, 1397/02/26

Registrant information

Name

Azar Fazaeli

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-27, 1396/04/06

Expected recruitment end date

2018-12-03, 1397/09/12

Actual recruitment start date

2017-10-08, 1396/07/16

Actual recruitment end date

2018-05-01, 1397/02/11

Trial completion date

empty

Scientific title

Effect of 810 nanometer (nm) low level diode laser irradiation on dental implant stability in posterior mandibular region .

Public title

Effect of low level diode laser on dental implant stability

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Need for posterior implant on the mandibular sides
Sufficient bone volume to receive implant without requiring bone augmentation(reconstruction)procedure in subject area

Exclusion criteria:

Pregnancy Smoking habits History of previous tooth extraction in the last six months in the selected area
System disease that effects osseointegration
Anticoagulant therapy Systemic glucocorticoid therapy
History of radiotherapy in the craniofacial region Acute infection in the mouth, uncontrolled or untreated periodontal disease Patients without good oral hygiene

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **28**

More than 1 sample in each individual

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

Patients with insertion at least two implants and more than one implant in bilaterally in the posterior mandible were included in the study.

Actual sample size reached: **28**

More than 1 sample in each individual

Actual sample size in each individual: **2**

A total of 28 implants were placed in eight patients following a split mouth design. the placebo group consisted of 14 implants and the laser group consisted 14 implants. Between 2 and 6 implants were inserted per patient, distributed bilaterally in the posterior mandible three patient received 2 implants (one at each side), one received six implants (three at each side), four patients received four implants (two at each side).

Randomization (investigator's opinion)

Randomized

Randomization description

After the surgery, one of the sides of the lower jaw of the patients was randomly (computer-generated random numbers) chosen to receive low level laser treatment (test group). The other side of the jaw was placebo, without any treatment performed and served as a control (control group).

Blinding (investigator's opinion)

Double blinded

Blinding description

All assessments of the study outcomes were performed in a double blind manner, since neither patients (due to placebo) or assessors (not involved in low level laser therapy) were aware of treatment allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Valiasr, Blvd, Golestan, Ahvaz Jundishapur University of Medical Sciences

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Postal code

6135715794

Approval date

2016-05-18, 1395/02/29

Ethics committee reference number

IR.AJUMS.REC.1395.196

Health conditions studied

1

Description of health condition studied

Dental implant stability

ICD-10 code

K08.1

ICD-10 code description

Complete loss of teeth

Primary outcomes

1

Description

Implant stability

Timepoint

Immediately after surgery and after 1, 3, 5 and 6 weeks

Method of measurement

Resonance Frequency Analysis (RFA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the group, diode laser 810(nm) (QuickLase, England) was irradiation by tissue probe from the buccal and lingual sides in contact without mucosa (40mw in 4 second) and repeated at 3, 7, 10, 14.

Category

Treatment - Devices

2

Description

Control group: laser irradiation was off

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Neda Rasaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Mousavi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Azar Fazaeli

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Corresponding to thesis

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable