

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3320 5170

##### Email address

fazaeli.a@ajums.ac.ir

##### 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

##### City

Ahvaz

##### Province

Khouzestan

##### 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

##### Street address

Valiasr, Blvd., Golestan

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azar.fazaeli@gmail.com

## 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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## Person responsible for scientific inquiries

#### Contact

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**Position**

Postgraduation Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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