# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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; Ahvaze 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 (tow 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 erradiation 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 irradeation 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
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6135715794
**Phone**
+98 61 3320 5170
**Fax**
+98 61 3336 1544
**Email**
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
**Street address**
Valiasr Blvd, Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3320 5170
**Fax**
+98 61 3336 1544
**Email**
azar.fazaeli@gmail.com
**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
**Street address**
Ahvaz Jundishapur University of Medical Sciences., Valiasr Blvd., Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3320 5170
**Fax**
+98 61 3336 1544
**Email**
azar.fazaeli@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Azar Fazaeli
**Position**
Postgraduation Student
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Dentistry
**Street address**
Valiasr, Blvd,Golestan, Ahvaz Jundishapur University of Medical Sciences
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3320 5170
**Fax**
+98 61 3336 1544
**Email**
azar.fazaeli@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Azar Fazaeli
**Position**
Postgraduate Student
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Dentistry
**Street address**
Valiasr., Blvd,Golestan., Ahvaz Jundishapur University of Medical Sciences
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61347-15794
**Phone**
+98 61 3320 5170
**Fax**
+98 61 3336 1544
**Email**
azar.fazaeli@gmail.com

## 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