

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Influence of postoperative low-level laser therapy using laser diode 940 nm on crestal bone levels around dental implants

#### Protocol summary

##### Study aim

Influence of postoperative low-level laser therapy using laser diode 940 nm on crestal bone levels around dental implants

##### Design

Randomization in the present study will be performed in Balance Block Randomization.

##### Settings and conduct

For each individual on the opposite side of a jaw in a region similar to each side of each side of an implant, and immediately using the mouse split method, the low-power laser of the diode is 940 nm in the power output of 0.5 watts with energy density J / cm<sup>2</sup> 6 in 6 areas. Around the implants of one side of the jaw receive radiation and does not receive any laser treatment and is considered as an area of control. In order to blind, laser tube is placed on both sides, but only laser laser. Craft's bone surface immediately after the placement of the implants (T0) after 6 weeks (T1) after 6 months (T2) and through parallel-in-oral periapic radiography with parallel technique.

##### Participants/Inclusion and exclusion criteria

The applicants of implant treatment that two-sided in a jaw in a similar area have lost tooth. Any systemic illness that contraindicates surgery.

##### Intervention groups

For each individual on the opposite side of a jaw in a region similar to each side of each side of an implant, and immediately using the mouse split method, the low-power laser of the diode is 940 nm in the power output of 0.5 watts with energy density J / cm<sup>2</sup> 6 in 6 areas. Around the implants of one side of the jaw receive radiation and does not receive any laser treatment and is considered as an area of control.

##### Main outcome variables

Cestal bone levels at 4 time 1) immediately after receiving of 940 nm laser (T0) 2) 6 weeks after receiving laser diode 940 nm (T1) 3) 6 months after receiving low-laser diode 940 nm (T2) Using parallel-based digital

periametic radiography, measured by parallel technique.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220205053946N1**

Registration date: **2022-05-09, 1401/02/19**

Registration timing: **retrospective**

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

##### Registration date

2022-05-09, 1401/02/19

##### Registrant information

##### Name

Shabnam Zarei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3433 5369

##### Email address

shabnamzare98@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-09, 1400/11/20

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Influence of postoperative low-level laser therapy using laser diode 940 nm on crestal bone levels around dental implants

### Public title

Influence of postoperative low-level laser therapy on crestal bone levels around dental implants

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

The applicants of implant treatment that two-sided in a jaw in a similar area have lost tooth. tooth extraction at least 6 months before implant surgery; nongrafted implant site; type 2 or 3 bone quality according to the Lekholm and Zarb classification, adequate space with buccolingual width of minimum 6 mm and mesiodistal width of minimum 7 mm; inter-occlusal distance greater than 7 mm.

#### Exclusion criteria:

Pregnant women. Any mental illness and psychological and behavioral conditions, which is the absolute contraindication of implant treatment. Any systemic illness that contraindicates surgery; uncontrolled diabetes mellitus; bisphosphonate therapy; history of radiotherapy in the maxillofacial region within last 12 months; smoking; para-functional habits; poor oral hygiene with full mouth plaque score and full mouth bleeding score  $\geq 25\%$ , periodontally compromised patients with attachment loss  $\geq 3$  mm, and/or radiographic bone loss  $\geq 30\%$  of root length in  $\geq 30\%$  of sites and those who refused to return for follow-up were excluded from this study.

### Age

From **20 years** old to **55 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **9**

More than 1 sample in each individual

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

Right and left in a jaw in a similar area

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

People participating in the study are aware of the laser treatment, but they are not aware of the quadrant that

the jaw is radiated. The oral and maxillofacial surgeon that performs implant treatment is not aware of the quadrant that the jaw is radiated. People who Evaluate the outcomes (student and the oral and maxillofacial radiologist) are not aware of the quadrant that the jaw is radiated. People who analyze the data ( Statistical specialist) is not aware of the quadrant that the jaw is radiated. Only the oral and teeth specialist who performs laser treatment will be aware of the quadrant that the jaw is radiated.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee Arak University of Medical Sciences

##### Street address

No.30, Shahid Shiroudi Ave, Alam-o-Alhoha ST, Arak, Iran

##### City

Arak

##### Province

Markazi

##### Postal code

3819693345

#### Approval date

2021-12-26, 1400/10/05

#### Ethics committee reference number

IR.ARAKMU.REC.1400.279

## Health conditions studied

### 1

#### Description of health condition studied

loss of teeth

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Measuring crestal bone levels around dental implants by radiography.

#### Timepoint

Crestal bone level at 4 time 1) immediately after receiving of 940 nm (T0) 2) 6 weeks after receiving laser diode 940 nm (T1) 3) 6 months after receiving low-laser diode 940 nm (T2) Using parallel-

based digital periapical radiography, measured by parallel technique.

#### **Method of measurement**

Using parallel-based digital periapical radiography, measured by parallel technique.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: An implant is placed on each side on opposite sides of a jaw in the same area, and immediately, using the split-mouth method, with a low-power 940 nm diode laser with a power output of 0.5 watts with 6 j/cm<sup>2</sup> energy density in 6 areas around one implant of one side of the jaw (control side), radiation is received. For blinding, the laser tube is placed on both sides, but only on one side of the laser will radiate. Crestal bone level is measured immediately after implant placement (T0), after 6 weeks (T1) and after 6 months (T2) by intraoral digital periapical radiography using a parallel technique. All surgeries are performed by an experienced surgeon with the same technique. All radiographs are performed in a specialized center for oral and maxillofacial radiology by an experienced specialist. All laser treatments are performed by an experienced specialist with the same technique. All patients use the same antibiotics and painkillers.

#### **Category**

Treatment - Surgery

### **2**

#### **Description**

Control group: The control group is actually the sides of the patients' jaw that is not exposed to the laser beam. Crestal bone level is measured immediately after implant placement (T0), after 6 weeks (T1) and after 6 months (T2) by intraoral digital periapical radiography using a parallel technique. All radiographs are performed in a specialized center for oral and maxillofacial radiology by an experienced specialist. All patients use the same antibiotics and painkillers.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Arak University of Medical Sciences, Faculty of dentistry

##### **Full name of responsible person**

Dr. Ehsan Momeni

##### **Street address**

Hepko Ave, Navab ST, Arak, Iran

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3817979438

##### **Phone**

+98 86 3369 1355

##### **Fax**

##### **Email**

daneshkadeha@arakmu.ac.ir

##### **Web page address**

<https://arakmu.ac.ir/school-dentistry/fa>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Alireza Kamali

##### **Street address**

No.2, Hepko Ave, Navab ST, Arak, Iran

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3848176341

##### **Phone**

+98 86 3417 3532

##### **Email**

alikalaliir@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Arak 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**

Arak University of Medical Sciences

##### **Full name of responsible person**

Dr. Ehsan Momeni

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

No2, Hepko Ave, Navab ST, Arak, Iran

**City**

Arak

**Province**

Markazi

**Postal code**

3817979438

**Phone**

+98 86 3369 1355

**Email**

momeni8384@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ehsan Momeni

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

No.2, Hepko Ave, Navab ST, Arak, Iran

**City**

Arak

**Province**

Markazi

**Postal code**

3817979438

**Phone**

+98 86 3369 1355

**Email**

momeni8384@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Shabnam Zarei

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

No.2, Hepko Ave, Navab ST, Arak, Iran

**City**

Arak

**Province**

Markazi

**Postal code**

3817979438

**Phone**

+98 86 3369 1355

**Email**

ShabnamZarei98@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available