Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Evaluating the effect of photobiomodulation therapy with 445 nm diode laser on peri-implant soft tissue healing following uncovering: a triple-blind, split-mouth, randomized controlled trial.

Protocol summary

Study aim

determination the effect of photomodulation treatment with 445 nm diode laser on the repair of soft tissue around the implant after the second stage surgery and to determine the patient's satisfaction with the treatment.

Design

This clinical trial is two-arms, with parallel groups, triple-blind, randomized, on 10 patients. For randomization, a randomization list will be prepared by the statistics consultant using the RAND function in Excel software and will be provided to the researcher.

Settings and conduct

This split-mouth, the triple-blind trial will be performed in a private office by a surgeon in 1401-1400. This study will be blinded in three directions. In this study, the patient, the evaluator (consisting of two periodontists, a maxillofacial surgeon who measures the outcomes of the study based on the EHS index), and the statistical analyst (statistics consultant) will be blinded in the intervention and control process.

Participants/Inclusion and exclusion criteria

Patients who have received dental implants in a two-stage method and bilaterally in one jaw will enter the study by considering the inclusion and exclusion criteria and signing a written informed consent form.

Intervention groups

After uncovering process, the surgeon will insert healing abutments (after three months)، suture the incision line with absorbable suture in simple interrupted method, on days zero (immediately after surgery), third, seventh, and fourteenth after surgery, patients will receive 445 nm blue diode laser by a laser operator (one of the researchers) in the buccal and lingual area will be exposed.

Main outcome variables

Early Wound Healing Score (by scoring the Early Wound Healing Index (EHS) in the data collection form) Patient evaluation of pain and discomfort in the surgical area (by scoring patients using the VAS ruler in the data collection form)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220119053766N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**

Registration date

2022-03-17, 1400/12/26

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of photobiomodulation therapy with 445 nm diode laser on peri-implant soft tissue healing following uncovering: a triple-blind, split-mouth, randomized controlled trial.

Public title
Evaluating the effect of photobiomodulation therapy with diode laser on peri-implant soft tissue healing following uncovering.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1) Patients who have received dental implants in a two-stage (conventional) method, bilaterally in one jaw(maxilla or mandible), and need healing abutment of a same size. 2) People over 18 years old. 3) No smoking, tobacco and other tobacco and alcohol consumption in the last six months. 4) Patients who have a good oral hygiene. (Patients are evaluated with O'Leary plaque index; and plaque index less than 10% is considered as good oral hygiene). 5) bleeding score less than 25% in 6 areas of each tooth 6) No history of periodontal treatment in the surgical area in the past year.
Exclusion criteria:
1) Patients with uncontrolled systemic disease (uncontrolled diabetes, immunodeficiency and uncontrolled periodontal disease). 2) Pregnant and lactating women. 3) People allergic to the drugs used in the study. 4) History of IV bisphosphonates consumption during the past three years and oral mode over ten years. 5) History of radiotherapy and chemotherapy in the head and neck area. 6) People who need advanced soft tissue management procedures (patients who have soft tissue defects or have extra soft tissue in the area). 7) Candidates of fresh socket implant method.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **8**
8 implant sites, two sided (4 in each quadrant).
Randomization (investigator's opinion)
Randomized
Randomization description
Using a simple randomized method, one side of the mouth is considered as the intervention area and the other side of the mouth is considered as the control. A randomization list will be prepared by the statistics consultant using the RAND function in Excel software and will be provided to the researcher. In the intervention area, the soft tissue around the desired dental implant will be exposed by laser. In the control area, the laser device probe will be used in off mode in the soft tissue area around the desired dental implant.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the patient, the evaluator (consisting of two periodontists and a maxillofacial surgeon who measures the outcomes of the study based on the EHS index), and the statistical analyst (statistics consultant) will be blinded by the intervention and control. During laser treatment, goggles are placed on the patient's eyes. The patient will not feel any heat changes or pain during the laser treatment. The device probe is used on the control side at the same time as intended on the intervention side in off mode. The patient (according to the above points) will be blind to which side of the mouth he receives the laser. The laser operator is not blind to the assignment of the laser to either side of the mouth, but the person measuring the results of the study will be blind to this assignment. Also, labels A and B are considered for both intervention and control so that the statistical analyst is blind to the end of the data analysis relative to the allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences-faculty of dentistry
Street address
North Karegar St,Tehran-Iran
City
Tehran
Province
Tehran
Postal code
149955991
Approval date
2021-10-30, 1400/08/08
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1400.155

Health conditions studied

1

Description of health condition studied
Evaluating the effect of photobiomodulation therapy with 445 nm diode laser on peri-implant soft tissue healing following uncovering
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Early Wound Healing Score (EHS)
Timepoint
Days 3, 7, 14 before the laser and also in the 21st day session
Method of measurement
By the Early Wound Healing Score (EHS) in the data collection form

Secondary outcomes

1

Description
Patient evaluation of pain and discomfort in the surgical area.
Timepoint
On each of the 3, 7, 14 days before the laser and also on the 21st day after surgery.
Method of measurement
Assessment of pain and discomfort in the surgical area, which is scored by the patient himself with a visual analog scale in the form of a 10 cm linear segment. The lowest score indicates the least pain and the highest score indicates the most pain and discomfort in the surgical area.

Intervention groups

1

Description
Intervention group:Initially, to start the process; local anesthesia with local infiltration technique in the maxilla or inferior alveolar nerve block in the mandible with 2% lidocaine anesthetic solution and epinephrine 1/100000 (Elixir Pharmaceutical Company, 1.8 ml)will be done . After uncovering by a surgeon with midcrestal incision and mucoperiosteal flap elevation and healing abutment insertion(after three months) with absorptive sutures (vicryl 000, 19 mm, reverse cut) by simple interrupted method (one in front And another behind the healing), on days zero (immediately after surgery), third, seventh and fourteenth after surgery with a 445 nm blue diode laser with specifications (SIRO Laser Blue, Sirona Dental SystemsGmbH, Bensheim, Germany) at a power of 200 mW and in continuous wave mode with handpiece therapy to a cross section of 0.5 cm2 for 15 seconds and a density energy of 6 J / cm2 will be irradiated by a laser operator (one of the researchers) in each of the two buccal and lingual areas.
Category
Treatment - Other

2

Description
Control group:In the control area, the laser device probe will be used in off mode in the soft tissue area around the desired dental implant
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک تخصصی دکتر دهقانی
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences- faculty of dentistry
Full name of responsible person
احمدرضا شمشیری
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خیابان کارگر شمالی، دانشکده دندانپزشکی دانشگاه علوم پزشکی تهران
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dent-research@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences- faculty of dentistry

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences- School of Dentistry

Full name of responsible person
Nima Dehghani

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
oral and maxillofacial surgery

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Position
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Latest degree
Specialist

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
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data file and statistical analysis will be shared

When the data will become available and for how long

3 months after data collection

To whom data/document is available

The above information will be made available to the public in the form of appendices along with the published article

Under which criteria data/document could be used

To better understand the study findings as well as a reference for future studies.

From where data/document is obtainable

website of the journal where the article will be published.

What processes are involved for a request to access data/document

The data file and statistical analysis will be available to everyone

Comments