Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of using low level laser therapy in management of the complications of guided bone regeneration(GBR) surgeries in patients who need this surgery

Protocol summary

Study aim
Determining the effect of low-level laser therapy as a post operative treatment in management of the complications of guided bone regeneration (GBR) surgeries .

Design
Clinical trial with a control group, with parallel groups, triple blinded, randomized, phase 3 on 22 patients. Computer random numbers are used for randomization

Settings and conduct
A clinic in the city of Ahvaz for referring patients After surgery, low-level laser therapy is performed and examinations related to the study are performed It is ensured that patients participate in the study with informed consent. Patients are blinded: they do not know whether the laser device is on or off clinical examiner is blinded: they are not aware of the group of each patient data analyst or statistical consultant is blinded: they will analyze the data of each group without knowing which group is the control and which is the intervention.

Participants/Inclusion and exclusion criteria
Patients beneath 60 years old who are medically healthy and in need of GBR surgery and not having photosensitivity

Intervention groups
For the intervention group, for each patient, the surgical site will be irradiated with a diode laser with a wavelength of 940 nm and a power of 300 mW and 16 seconds for each cm2 of the lesion, immediately after the end of surgery and 48 hours after the surgery. (The required dose for laser therapy is 5 j/□cm□^2, there is 16 seconds of radiation needed for each cm2). In the control group, laser irradiation is performed with the device turned off at the same time as the intervention group

Main outcome variables
severity of pain The degree of inflammation Wound healing Homeostasis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221023056272N1**
Registration date: **2023-04-29, 1402/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-29, 1402/02/09**
Update count: **0**

Registration date
2023-04-29, 1402/02/09

Registrant information

Name
Asma Moghadasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 933 177 4942

Email address
moghadasi.a@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-05-22, 1402/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of using low level laser therapy in management of the complications of guided bone regeneration(GBR) surgeries in patients who need this surgery

Public title
Evaluation the effect of low level laser therapy in management of the complications after guided bone regeneration(GBR) surgeries.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients must be medically healthy Having healthy oral mucosa. Not having the history of implant failure at the surgical site or contraindications for implant placement Patients must be in need of bone grafting for placement of implant Cases, with maximum 0.5cc bone powder required for bone grafting, are going to be chosen The surgical field should be limited to 1 to 3 teeth Patients should not use removable prosthesis or similar items No history of medical conditions that might delay wound healing process such as: diabetes, smoking, and alcohol consumption.

Exclusion criteria:
Lack of Patient's cooperation Having photosensitivity Patients who have used antibiotics and corticosteroids for any reason in the last 2 weeks

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
A list of 22 characters consisting of 11 characters A (representative of the laser radiation group) and 11 characters B (representative of the group without laser radiation (placebo)) is created by simple randomization using the envelope-in-package method, and the patients are placed in one of groups A or B according to the order of their referral

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participant: For all the people participating in the study, the laser irradiation process is performed , the difference is that for the intervention group, the laser irradiation process is performed with the laser on, and for the control or placebo group, the laser irradiation process is performed with the laser off. Outcome assessor (clinical examiner): the clinical examiner does the patient's examination without being aware of the patient's group and records the necessary information. Data analyst: The data analyst or statistical consultant will analyze the data of each group without knowing witch group is the control and which is the intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahwaz University of Medical Sciences

Street address
4th Floor ,No.12, Elham sharghi Street. Kianpars Street

City
Ahwaz

Province
Khouzestan

Postal code
6155843651

Approval date
2023-04-08, 1402/01/19

Ethics committee reference number
IR.AJUMS.REC.1402.014

Health conditions studied

1

Description of health condition studied
Post-operative complications of guided bone regeneration

ICD-10 code
T88.8XXA

ICD-10 code description
Other specified complications of surgical and medical care, not elsewhere classified, initial encounter

Primary outcomes

1

Description
The VAS(visual analog scale) number of pain intensity declared by patients

Timepoint
At 12, 24, 48, 72 hours after surgery

Method of measurement
based on VAS (visual analog scale)

2

Description
The assigned number of the hemostasis status
Timepoint
On second day after surgery
Method of measurement
The number assigned to each hemostasis status is based on the following classification: 0 for the presence of bleeding in the wound margin/1 for the presence of fibrin in the wound margin/2 for the absence of fibrin in the wound margin.

3

Description
Determining the degree of wound healing based on assigned numbers
Timepoint
On the seventh day after surgery
Method of measurement
Wound healing is graded as follows: 0 for complete wound healing / 1 for wound healing and the presence of a thin line of fibrinous membrane / 2 for wound healing and the presence of fibrin / 3 for incomplete wound closure and the presence of a gap/ 4 no wound healing (necrosis)

4

Description
Determining the degree of inflammation based on two factors: 1) the degree of redness of the wound margin 2) presence or absence of extraoral swelling
Timepoint
On the second and seventh day after surgery
Method of measurement
To check the redness of the wound margin, the following grading is used: 0 for redness over 50% of the length of the wound margin / 1 for redness less than 50% of the length of the wound margin / 2 no redness

Secondary outcomes

1

Description
The number and dose of painkillers taken by the patient
Timepoint
On seventh day after surgery
Method of measurement
After the surgery, the patient is given a table and asked to make notes in the table after receiving each painkiller. And the table is delivered on the seventh day

Intervention groups

1

Description
Intervention group: Laser radiation: In the laser radiation group, immediately after the surgery for each patient, the surgical site will be irradiated with Diode laser with a wavelength of 940 nm and a power of 300 mW and 16 seconds for each cm2 of the lesion. The necessary dose for laser therapy is 5 j/□cm□^2 (we will have 16 seconds of radiation for each cm2). According to the explained method, the same amount of energy is again irradiated to the desired area 48 hours after the surgery.
Category
Treatment - Devices

2

Description
Control group: In the control group, laser irradiation is performed with the device turned off at the same time as the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arad dental clinic
Full name of responsible person
Dr. Ebrahim Moghadasi
Street address
No. 50, West 3, Kianpars Streat, Ahwas town
City
Ahwaz
Province
Khouzestan
Postal code
6155843651
Phone
+98 61 3338 4393
Email
emog9933@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerhoseini
Street address
Ahvaz Academic City - Vice President of Research and Technology University of Medical Sciences and Jandi Shapur Health Services, Ahvaz - ground floor
City
Ahwaz
Province
Khouzestan
Postal code
6135715775
Phone
+98 61 3336 2414
Email

itc@ajums.ac.ir

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

Asma Moghadasi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Floor. 2, No. 12, East Elham, Kianpars Street

City

Ahwaz

Province

Khouzestan

Postal code

6155843651

Phone

+98 61 3333 5830

Email

asma.moghadasi98@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Asma Moghadasi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

East elham, kianpars streat, Ahwaz town

City

Ahwaz

Province

Khouzestan

Postal code

6155843651

Phone

+98 933 177 4942

Fax

Email

moghadasi.a@ajums.ac

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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+98 61 3333 5830

Email

asma.moghadasi98@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

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available