

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Diode Laser (940 nm) and Scalpel's Morbidity in Second Stage of Implant Surgeries

Protocol summary

Study aim

Determination of laser diode (940nm) and scalpel morbidity in second stage implant surgeries

Design

Randomized two-arm parallel, double-blind trial, sample size 40.

Settings and conduct

The subjects are divided equally and randomly into two groups of intervention (940 diode laser in the second stage of implant surgery) and control (surgical scalpel (scalpel) with punch technique in the second stage of implant surgery). In the control group (scalpel) After applying sufficient local anesthesia, a circular incision with an approximate diameter of 2-3 mm is given on the soft tissue above the head of the implant with razor number 15. After determining the exact position of the implant, a circular incision is made wider. In the intervention group (laser diode), the second stage of implant surgery is performed using a 940 nm diode laser. The laser is used to create a small hole until a part of the screw cover appears. It is then large enough to allow the screw to be removed. Hours after surgery, second stage implants are called in to assess pain (on the VAS index scale), duration of surgery (in minutes), and after 1 week on tissue repair (on the wound healing index).

Participants/Inclusion and exclusion criteria

Inclusion criteria also include: implants that are loaded late, the presence of healthy keratinized gingival tissue at least 3 mm after surgery. Exclusion criteria: failed implant placement, inflammation around the implant peri-implantitis.

Intervention groups

Intervention group: Second stage surgery with scalpel method (surgical razor blade), this technique is performed routinely and is not considered a new intervention. Control group: Second stage surgery by laser method of 940 diode by the device (EPIC 10, biolase; in a contact mode with a maximum power of 2.4 W in CP2 mode and E4 tip type).

Main outcome variables

the pain ;Duration of surgery;Tissue healing.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211114053062N1**

Registration date: **2022-03-12, 1400/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-12, 1400/12/21**

Update count: **0**

Registration date

2022-03-12, 1400/12/21

Registrant information

Name

Shabnam Sanayei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3337 3788

Email address

drsanayei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-05-07, 1401/02/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Diode Laser (940 nm) and Scalpel's Morbidity in Second Stage of Implant Surgeries

Public title

Comparison of Diode Laser (940 nm) and Scalpel's Morbidity in Second Stage of Implant Surgeries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

delayed loading dental implant delayed insertion dental implant two stage protocol of dental implant healthy keratinized gingival tissues at least 3 mm

Exclusion criteria:

failed dental implant inflammation or peri-implant inflammation radiolucent line around the dental implant

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are entered into the study based on entry and exit criteria using available sampling and will be randomly assigned to one of the two control and intervention groups within each block using the random blocking method. The size of each block is equal. It will be with two, four or eight samples. After completing each block of treatments, people will be applied based on a random shift of treatments. Blocks and permutations within each block using the agricolae package (statistical procedure for agricultural research) in R software and using a specific seed (in computer concepts, in order to reproduce each random sequence, an optional number called seed is used).) Will be created. The seed number allows the reproduction of a random sequence. Based on this package, the block number, block size, sequence within each block and the type of treatment of each person are provided as software output.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the patient, all surgical descriptions and complete information are given in written and oral form, ethically announced in the ethics committee and registered with the number IR.QUMS.REC.1400.218. They will be performed with full knowledge. In this study, patients have no information about the type of surgery they will receive. The surgery will be performed by a perio

specialist and then the duration of the surgery will be recorded by an expert who does not know the type of surgery. Also, the healing rate of patients one week after surgery will be recorded by another specialist who does not know the type of surgery, and also for VAS.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin Shahid Bahonar Blvd.Qazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.QUMS.REC.1400.218

Health conditions studied**1****Description of health condition studied**

The amount of pain and duration of surgery and tissue repair after surgery in the second stage.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain rate

Timepoint

Patients in both groups are called at 24 hours, 48 hours and 72 hours after the second stage of implant surgery to be evaluated for pain (with Visual Analogue Scale).

Method of measurement

Patients in both groups are called at 24 hours, 48 hours and 72 hours after the second stage of implant surgery to be evaluated for pain (with Visual Analogue Scale).

2

Description

duration of surgery.

Timepoint

From the beginning of the laser to the end, from the beginning of the cut to the end.

Method of measurement

From the beginning of the laser to the end, from the beginning of the cut to the end.

3

Description

tissue repair

Timepoint

After 1 week, its amount in tissue repair (with wound healing index)

Method of measurement

After 1 week, its amount in tissue repair (with wound healing index)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Second stage surgery using a scalpel or 15c surgical scalpel, which is performed routinely and is not considered a new intervention. A circular incision is made on the top of the implant head and the healing abutment is closed without the need for sutures. A circular incision with an approximate diameter of 2-3 mm is given on the soft tissue above the implant head with a razor number 15. Depending on the exact position of the implant, a circular incision is made later until the full cover screw appears and then healed.

Abutment is connected. In the intervention group (diode laser), the second stage of implant surgery is performed using a 940 nm diode laser. The laser is used to create a small hole until a part of the screw cover appears. Then it is large enough to allow the screw to be removed, so the implant screw cover is removed and the abutment healer is connected.

Category

Treatment - Other

2

Description

Intervention group 2: Second stage surgery using 940 laser diode by the device (EPIC 10, biolase; as contact mode with maximum power 2.4 W with CP2 mode and E4 tip type). Creates a circular incision on the top of the implant head and closes the healing abutment without Need suture.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Science

Full name of responsible person

Shabnam Sanayei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Qazvin 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

drsanayei@gmail.com

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Shabnam Sanayei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Full name of responsible person

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Position

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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