Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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
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Iran (Islamic Republic of)
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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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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

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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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