

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of low-level laser on complications after crown lengthening surgery in premolars

Protocol summary

Study aim

Evaluation of the effect of low level laser on tissue edema, tissue color and pain intensity after crown lengthening surgery in premolars

Design

Split Mouth, double blind, two arm parallel group controlled clinical trial on 12 patients with simple randomization method

Settings and conduct

This study was performed in Birjand Dental School. After crown lengthening surgery, In the intervention areas low level laser irradiation was performed immediately after surgery, one and three days after surgery. There was a gap of at least two weeks between the two surgeries. In the control areas, the device was placed in the mouth but it was turned off and no irradiation was performed. Tissue edema and tissue color were measured one, three and seven days after surgery and pain intensity was measured 24, 48 and 72 hours after surgery. Participants and the examiner were blind. The sealed envelope containing the position of the intervention recipient side was handed directly to the laser irradiator without the examiner's notice. The device used in this study did not produce any signals that alerted the patient to irradiation or no irradiation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The need for crown lengthening surgery on at least two bilateral premolars without gingivitis; 18 to 60 years of age; informed consent. Exclusion criteria: Systemic diseases affecting wound healing; smoking; long-term use of corticosteroids and antibiotics; pregnancy and lactation; lack of informed consent.

Intervention groups

The intervention in this study was low level laser irradiation that was randomly performed on one side of the jaw. the other side was assigned to the control group. On the intervention side, the laser was irradiated after surgery, and on the control side, no irradiation was

performed.

Main outcome variables

Tissue edema, Tissue color, Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220508054774N1**

Registration date: **2022-05-25, 1401/03/04**

Registration timing: **retrospective**

Last update: **2022-05-25, 1401/03/04**

Update count: **0**

Registration date

2022-05-25, 1401/03/04

Registrant information

Name

Sajjad Abedzade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3876 9719

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-04, 1399/08/14

Expected recruitment end date

2021-08-05, 1400/05/14

Actual recruitment start date

2021-02-23, 1399/12/05

Actual recruitment end date

2022-03-14, 1400/12/23
Trial completion date
2022-03-14, 1400/12/23

Scientific title
The effect of low-level laser on complications after crown lengthening surgery in premolars

Public title
The effect of low-level laser on complications after crown lengthening surgery in premolars

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The need for crown lengthening surgery on at least two premolars without gingivitis on both sides of the jaw
Informed consent
Exclusion criteria:
Suffering from systemic diseases affecting wound healing Smoking Long-term use of corticosteroids and antibiotics Pregnancy and lactation Lack of informed consent

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: **12**
More than 1 sample in each individual
Number of samples in each individual: **2**
Bilateral crown lengthening surgery of premolars in each individual
Actual sample size reached: **12**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Bilateral crown lengthening surgery of premolars in each individual

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with sealed envelope method. Numbers (from 1 to 12) were written for the expected number of patients and placed in a sealed envelope. After drawing, in the first half of the numbers that came out, the intervention area was considered on the right side and in the other half, on the left. Then, based on the time of admission of patients to the study, each patient was assigned a number Sequentially.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants and the examiner were considered blind. The paper containing the number assigned to each patient and the position of the intervention recipient side were handed directly to the

laser irradiator in sealed envelopes without the examiner's notice. The laser device used in this study did not produce any signals that alerted the patient to irradiation or no irradiation.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Ghafari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Approval date
2020-10-12, 1399/07/21
Ethics committee reference number
IR.BUMS.REC.1399.326

Health conditions studied

1
Description of health condition studied
Crown lengthening surgery of premolars
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
The amount of tissue edema
Timepoint
One, three and seven days post-surgery
Method of measurement
Clinical examination checklist

2
Description
Tissue color
Timepoint
One, three and seven days post-surgery
Method of measurement

3**Description**

Pain intensity

Timepoint

24, 48 and 72 hours post-surgery

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this Split-Mouth study, the intervention was low-level laser irradiation. After crown lengthening surgery in each patient, on the intervention side laser was irradiated. The AlGaAS 808nm diode laser was applied to the surgical area in parallel paths from coronal to apical with a power of 0.25 watts, an energy density of 4 joules per square centimeter using continuous irradiation settings.

Category

Treatment - Devices

2**Description**

Control group: In each patient, after crown lengthening surgery, on the control side laser device was placed in the mouth to resemble the irradiation for the patient, but in fact the device was turned off and no irradiation was performed. (Placebo)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Birjand dental school

Full name of responsible person

Dr. Narjes Akbari

Street address

Between Pasdaran 1 & 3 alley, Pasdaran Blvd.

City

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South Khorasan

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9717853577

Phone

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Email**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Toba Kazemi

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9717853577

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Sajjad Abedzade

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No. 36, Razavi 6 st., Razavi Blvd., Rezashahr

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Sajjad Abedzade

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

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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

Not applicable

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main result and patient dental documents can be shared. Informed consent form, clinical study results, study protocol and codes used in the study are fully available.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Changes in primary outcomes cannot be cited in other studies because they are time-dependent. The final results of the study provide a suggestion for more detailed studies with greater scope and longer follow-up.

From where data/document is obtainable

Dr. Marzieh Mohammadi Moghaddam:
mohamadi_moghadam@yahoo.com Sajjad Abedzade:
g.abedzade@gmail.com

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

Sending an email, containing the name of the researcher, the title of the study or the reason for interest, and documents related to the academic researcher, if we see the email, the documents will be sent up to you one month later.

Comments