Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+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

۹۷۱۷۸۵۳۵۷۷

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

Clinical examination checklist

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.
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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drtooba.kazemi@gmail.com
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
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g.abedzade@gmail.com

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