Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Low Level Laser Therapy on post operative pain after clinical crown lengthening procedures

Protocol summary

Study aim
The purpose of this study is to evaluate the effect of low level laser therapy on post operative pain after clinical crown lengthening procedures.

Design
two arm parallel group randomized clinical trial, one way blinded. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site.

Settings and conduct
the patients will be selected from visitors of dentistry faculty of tabriz university of medical sciences and private practice office. after conducting the surgery the patient will be treated with either low lever laser or plasbo laser according to which group they are in. appointments will be given for 3 and 7 days after surgery for further steps. for pain evaluation a quastionnaire will be used and patients will be asked of their pain up to 10 days after surgery. also the amount of pain relieving medication they are taking will be asked.

Participants/Inclusion and exclusion criteria
inclusion criteria are: having age of between 18 and 60 years, not having systemic conditions and good oral hygiene. exclusion criteria are being a smoker, having systemic conditions and drug induced gum hyperplasia.

Intervention groups
in the intervention group, low level laser with GaAlAs diode laser with 100 milliwatts power and energy density of 4 jules per square centimeters and wave length of 660 nano meters is used at the day of surgery, 3 days after surgery and 7 days after surgery each time for duration of 30 seconds on the site of surgery. in the control group the laser is used in the same manner but it is deactivated and is held on the surgery site for 30 seconds.

Main outcome variables
amount of post operative pain; amount of prescribed pain relieving medication taken for post operative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180114038364N1**
Registration date: **2020-05-02, 1399/02/13**
Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**
Update count: **0**

Registration date
2020-05-02, 1399/02/13

Registrant information

Name
Mehrnoosh Sadighi Shamami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3335 5965

Email address
mehrnoosh1378@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-08-20, 1399/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of Low Level Laser Therapy on post operative pain after clinical crown lengthening procedures

Public title
effect of low level laser therapy on postoperative pain in gum surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
the patients must be between 18 and 60 years of age patients must not have systemic conditions patients must have adequate oral hygiene
Exclusion criteria:
if the patient is a smoker. if the patient has systemic conditions. if the patient has drug induced gum hyperplasia.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
randomization will be individually and simple. using the table of randomized numbers, each individual will be put in either of the laser therapy or control groups. Odd numbers will be assigned to the intervention group and even numbers will be assigned to the control group. the analyst will move in a specific direction in the table in one row or column and assign the numbers to the patients. the surgeon and the researcher will not know the patient's group until the surgery is over. after the surgery, the researcher will know the individual's code number and if the code is an odd number then patient will be referred for low level laser therapy and if the code number is an even number, the patient will be referred for placebo laser therapy.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is designed as one way blind and the patients will be blinded. all the participants in the study will be informed that they will receive low level laser therapy after the surgery so that the effect of laser on post operation pain is evaluated. same information and instructions will be given to all the patients regarding the laser therapy. in the laser therapy group, the laser is applied with a specific dose and specific duration and within a specific distance from the site of surgery. in the control group the same laser will be held for the same duration and same distance from the surgery site but the laser is not active and the patient will not be informed that the laser is not active.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tabriz university of medical sciences
Street address
No. 96, 3rd hafez avenue, eil goli boulevard, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166884461
Approval date
2020-03-09, 1398/12/19
Ethics committee reference number
IR.TBZMED.REC.1398.1299

Health conditions studied

1

Description of health condition studied
post operative pain
ICD-10 code
G89.18
ICD-10 code description
other acute post procedural pain

Primary outcomes

1

Description
The amount of post operative pain on a scale of 0 to 10
Timepoint
Daily up to 10 days after the day of surgery
Method of measurement
Using Visual analogue scale (VAS)

2

Description
amount of usage of prescribed pain relieving medication
Timepoint
Daily up to 10 days after surgery
Method of measurement
Asking the patient whether they took the prescribed pain relieving medication and if yes how many.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: a diode GaAlAs laser with a power of 100 milliwatts, wave length of 660 nano meters and energy density of 4 jules per square centimetres will be used on the surgery site for a duration of 30 seconds. this will be done at the day of surgery, 3 days after surgery and 7 days after surgery.
Category
Treatment - Devices

2

Description
Control group: a diode GaAlAs laser(same with the intervention group) will be used deactivated on the site of surgery for 30 seconds. this will be done at the day of surgery, 3 days after surgery and 7 days after surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry faculty of tabriz university of medical sciences
Full name of responsible person
Sina Ranjbaraghdam
Street address
End of golgasht st. , daneshgah st, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Phone
+98 41 3335 5965
Email
dent.fac@tbzmed.ac.ir
Web page address
https://dentistryfac.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
mohammad samiei
Street address
Third floor, Central building no.2, Tabriz university of medical sciences, golgasht st, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
+98 41 3335 7310
Email
Samiei.moh@gmail.com
Web page address
https://researchvice.tbzmed.ac.ir/page/0/%d9%85%d8%b9%d8%b1%d9%81%db%8c-%d9%88-%d8%b4%d8%b1%d8%ad-%d9%88%d8%b8%d8%a7%db%8c%d9%81-%d9%85%d8%b9%d8%a7%d9%88%d9%86%d8%aa-%d8%aa%d8%ad%d9%82%db%8c%d9%82%d8%a7%d8%aa-%d9%88-%d9%81%d9%86%d8%a7%d9%88%d8%b1%db%8c.html
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Sina Ranjbaraghdam
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
no 96, 3rd hafez avenue, eil goli boulevard, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code

5166884461

Phone
+98 41 3383 1992

Email
ranjbar.sinara.sina576@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Sina Ranjbaraghdam

Position
student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

Street address
no 96, 3rd hafez avenue, eil goli boulevard, Tabriz

City
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Province
East Azarbaijan

Postal code
5166884461

Phone
+98 41 3383 1992

Email
ranjbar.sinara.sina576@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Sina ranjbraghdam

Position
student

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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no 96, 3rd hafez avenue, eil goli boulevard, Tabriz

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Province
East Azarbaijan

Postal code
5166884461

Phone
+98 41 3383 1992

Email
ranjbar.sinara.sina576@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
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