

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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 questionnaire 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 GaAIAs 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 GaAIAs 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

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Tabriz

#### Province

East Azarbaijan

#### Postal code

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#### 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

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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**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**

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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