

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of the effect of 808 nm low level laser on reversing the effect of inferior alveolar nerve block in 6-9 years old children

#### Protocol summary

##### Study aim

determining the effect of 808 nm low level laser on reversing the effect of inferior alveolar nerve block in 6-9 years old children

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, sealed envelopes were used for randomization.

##### Settings and conduct

34 children aged 6-9 years with decayed teeth, who are indicated for pulpotomy on both sides of the mandible and are systemically healthy, with Frankel cooperation level 3 and 4 are selected as samples. Inferior alveolar nerve block is applied to them and after performing the pulpotomy treatment and after 30 minutes of applying the laser block with a wavelength of 808 nm, a point in the anesthesia injection area is irradiated. The return of the anesthetic effect was measured by touching the area and by the child's statements, and its time was recorded. On the opposite side, the laser device is placed in the area without radiation, and as a control group, it is compared with the other side in terms of the return time of the anesthesia effect and the possibility of trauma caused by biting after 24 hours. Sealed envelopes were used to determine the order of the intervention.

##### Participants/Inclusion and exclusion criteria

- Children with scores of 3 and 4 based on Frankel's behavioral rating scale.
- Children aged 6 to 9 have the ability to understand and respond to soft tissue sensations.
- Patients who need pulpotomy treatment of left and right mandibular molars under inferior alveolar nerve anesthesia.

##### Intervention groups

experimental group: 808 nm laser control group: off mod laser

##### Main outcome variables

reversal of anesthesia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210914052474N2**

Registration date: **2023-01-04, 1401/10/14**

Registration timing: **prospective**

Last update: **2023-01-04, 1401/10/14**

Update count: **0**

##### Registration date

2023-01-04, 1401/10/14

##### Registrant information

##### Name

Fatemeh Shekarchi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2217 5350

##### Email address

f.shekarchi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-20, 1401/12/01

##### Expected recruitment end date

2023-05-20, 1402/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of 808 nm low level laser on reversing the effect of inferior alveolar nerve block in 6-9 years old children

#### Public title

the effect low level laser on reversing the effect of inferior alveolar nerve block

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Children 6-9 years old without systemic disease Children with Frankel level 3 and 4 Patients who need pulpotomy of left and right mandibular primary molars under inferior alveolar nerve block.

##### Exclusion criteria:

history of sensitivity to anesthetics and sulfate errors in the injection of anesthesia during the study.

#### Age

From **6 years** old to **9 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **34**

More than 1 sample in each individual

Number of samples in each individual: **2**  
mandibular primary molars

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The study was conducted in a split-mouth manner, and sealed envelopes were used for randomization. In this way, envelopes are first randomly selected to determine the side under laser radiation. Then envelopes are selected to determine the type of intervention (or control) in the first session.

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

Patient is blinded by putting shield glasses on his/her eyes and thus he/she is unaware about the activation of the laser device. Result assessor is unaware about which method is used in the session and will only enters the pain score and so on he/she is blinded. The data is given to the analyzer by certain codes and he analyzes only the codes without knowing about their nature.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

no. 3, Nikkhu alley, Tabriziar ave., Mirdamad Blvd.

##### City

Tehran

##### Postal code

3413865761

#### Approval date

2022-11-14, 1401/08/23

#### Ethics committee reference number

IR.SBMU.DRC.REC.1401.059

## Health conditions studied

### 1

#### Description of health condition studied

anesthesia

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The duration of the anesthesia

#### Timepoint

45 minutes after injection and then every 10 minutes

#### Method of measurement

touching by a sharp object

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: low level laser konftec 808 nm 6.3 J, 23s on every point will be used on 12 point (6 point intra-oral and 6 point extra-oral) 45 minutes after block injection.

#### Category

Treatment - Devices

### 2

#### Description

Control group: off mod laser will be located on 12 points like intervention group

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
dental school of shahid beheshti university  
**Full name of responsible person**  
Fateme Shekarchi  
**Street address**  
no.3 Tabrizian Avn., Mirdamad Blvd  
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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Afshin Zarghi  
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Shahid Beheshti Dental School, Daneshjoo Blvd,  
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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**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Fateme Shekarchi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Latest degree**

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**Other areas of specialty/work**

Dentistry

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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**

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

the recorded data can be shared based on the studied indicators after identifying the samples individuals. these data include the numbers and scores reported from sensitivity to touch and trauma due to biting.

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

researchers working in academic and scientific institutes can apply for access to data.

**Under which criteria data/document could be used**

performing statistical analysis to compare data with other studies this field is one of the conditions for access to data, so the analysis must be appropriate to the type of data received from the applicant.

**From where data/document is obtainable**

The applicant can apply for access to the data via email zahra\_kia\_ss@yahoo.com.

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

after submitting the request by e-mail, the applicant will be able to access the information within one week after submitting the request, if has the request conditions.

**Comments**