

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluating the efficacy of low level laser therapy in decreasing the injection pain and post treatment pain in primary teeth

#### Protocol summary

##### Study aim

Evaluating the efficacy of low level laser therapy in decreasing the injection pain and post treatment pain in primary teeth

##### Design

Randomized clinical trial, split mouth, with crossover groups, triple blinded, over 30 patients, randomization achieved by SNOSE method.

##### Settings and conduct

In children within age of 6 to 9 year old visiting pediatric section of shahid beheshti dental school, requiring pulpotomy treatment in both E teeth of the maxilla and anesthesia with infiltration technique, in first session, a saline cotton is used to the site of injection and then low level laser is radiated to the site and the injection is performed. In the next session, a cotton smeared with topical anesthesia gel is used on the site of injection, and then the laser device is pointed to the site while the power is off, and then the injection is performed. At the end of each injection, the severity of pain is assessed by the Visual Analogue Scale.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Need of pulpotomy treatment for both upper jaw E teeth requiring infiltration injection No history of bad dental treatment Children within age of 6 to 9 year old Exclusion criteria: Systemic disease Allergy to anesthesia drug Inflammation in the site of injection No consent of parents to participate in the study

##### Intervention groups

First Intervention group: radiation of low level laser therapy on tooth E of the maxilla on one side of a patient  
Second Intervention group: use of topical anesthesia gel on tooth E of the maxilla on the other side of the same patient

##### Main outcome variables

Severity of pain during injection Severity of pain after the removal of anesthesia after 1 hour and 24 hours of the treatment

#### General information

##### Reason for update

##### Acronym

LLLT

##### IRCT registration information

IRCT registration number: **IRCT20210914052474N1**

Registration date: **2021-11-04, 1400/08/13**

Registration timing: **prospective**

Last update: **2021-11-04, 1400/08/13**

Update count: **0**

##### Registration date

2021-11-04, 1400/08/13

##### 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

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-01-05, 1400/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluating the efficacy of low level laser therapy in decreasing the injection pain and post treatment pain in primary teeth

## Public title

Evaluating the efficacy of low level laser therapy in decreasing the injection pain and post treatment pain in primary teeth

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Need of pulpotomy treatment in bilateral first primary molar teeth of upper jaw requiring infiltration anesthesia  
No record of bad dental treatment in the past Children within age of 6 to 9 year old

### Exclusion criteria:

Systemic disease Allergy to local anesthesia drug  
Inflammation in the site of injection  
No consent of the parents to participate in 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: **30**

## Randomization (investigator's opinion)

N/A

## Randomization description

## 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

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Research institute of dental sciences- Shahid Beheshti university of medical sciences

## Street address

No. 4, Moqadam close, South Ramin St, East Ferdows Blvd

## City

Tehran

## Province

Tehran

## Postal code

1481999586

## Approval date

2021-03-01, 1399/12/11

## Ethics committee reference number

IR.SBMU.DRC.REC.1399.150

## Health conditions studied

### 1

#### Description of health condition studied

Low level laser therapy in primary teeth

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Severity of pain during injection

#### Timepoint

During injection

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Severity of pain after removal of anesthesia

#### Timepoint

1 hour and 24 hours after removal of anesthesia

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First Intervention group: Low level laser therapy

#### Category

Treatment - Devices

### 2

#### Description

Second Intervention group: Topical anesthesia gel  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Beheshti dental school

**Full name of responsible person**

Fatemeh Shekarchi

**Street address**

Shahid Beheshti dental school, Daneshjoo Blvd,  
Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 2217 5351

**Email**

fshekarchi92@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Shahid Beheshti Dental School, Daneshjoo Blvd,  
Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2203 2387

**Email**

Zarghi@sbmu.ac.ir

**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**

70

**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**

Fatemeh Shekarchi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Fatemeh Shekarchi

**Position**

Associate professor

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Specialist

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## Person responsible for updating data

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Shahid Beheshti 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**

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 sample individuals. These data include the numbers and scores reported from the Wong Baker FACES pain rating scale, and numbers recorded from the finger pulse oximeter at specified times, as well as results of statistical analysis of these data.

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

e.g., starting 6 months after publication

**To whom data/document is available**

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

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

Performing statistical analyzes to compare data with other studies in 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**

Applicants can obtain access to the data by submitting a request to the following email addresses in due time:  
soroush.amn@yahoo.com fshekarchi92@gmail.com

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

After submitting the request by email, the applicant will be able to access the information within one week after submitting the request, if he/she has the requisite conditions.

**Comments**