Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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1983969411

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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

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1983963113

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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 updating data

Contact

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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