

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Pain reduction during infiltration injection of maxillary deciduous molar teeth by low level laser in 4-9 years old children

Protocol summary

Registration timing: **prospective**

Study aim

Pain reduction during infiltration injection of maxillary deciduous molar teeth by low level laser in 5-9 years old children referred to pediatric ward of dentistry school of Tehran university of medical science in 2018

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Design

This research is Randomized clinical trial. The sample size is 64 children between 5 to 9 years old. The randomization is done with the help of 4 numeric random blocks by Excel software.

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

88015950 54 الی

Email address

a-bavaghar@student.tums.ac.ir

Settings and conduct

64 children between 5 to 9 years old referred to pediatric ward of dental school of Tehran university of medical science will be chosen. The study is Randomized clinical trial. Patient, care provider and information resistant will not be informed about the application of laser which is on or off.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Age between 5 to 9 Frankel's behavioral rating scale 3 or 4 Stainless steel crown (SSC) or Extraction treatment is required No systematic problem No psychological disorder No lesion in intended tooth No pain or infection history in intended tooth No use of pain killers at least 24h before treatment

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01

Intervention groups

In experimental group, the mucus is smeared with local anesthetic gel and then undergoes laser radiation. In control group, the situation is the same but laser device is on off mood.

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Pain level

Trial completion date

empty

General information

Scientific title

Pain reduction during infiltration injection of maxillary deciduous molar teeth by low level laser in 4-9 years old children

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037264N2**

Registration date: **2018-09-18, 1397/06/27**

Public title

Pain reduction by Laser

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 5 to 9 years old Frankel's Behavioral Rating Scale 3 or 4 SSC or Extraction treatment is required No psychological problem No pain or infection history in the intended tooth No use of pain killers at least 24 h before treatment

Exclusion criteria:

Inappropriate cooperation Systematic disease Lesion in the intended tooth Parents disagreement

Age

From **5 years** old to **9 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

This research is randomized clinical trial.with the help of 4 numeric random blocks ,by Excel software

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant, care provider,investigator and outcome assessor will not be informed about the application of laser which is on or off.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of dental school of Tehran university of medical science

Street address

North Amirabad street, front than Iran atomic energy organization .Dental school of Tehran university of medical science,Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2018-07-11, 1397/04/20

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1397.048

Health conditions studied

1

Description of health condition studied

Pain reduction during infiltration injection of maxillary deciduous molar teeth by low level laser in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The pain experienced by 100 mm Visual analogue scale(100mmVAS)

Timepoint

The pain experienced is measured right after the injection .

Method of measurement

The pain experienced is measured by 100mmVAS scale.

2

Description

Child's behavior by Modified behavioral pain scale (MBPS)

Timepoint

Child's behavior is measured during local anesthetic solution injection.

Method of measurement

Modified behavioral pain scale (MBPS)

Secondary outcomes

1

Description

Pain reduction injection

Timepoint

Right after the intervention

Method of measurement

By 100mm VAS

Intervention groups

1

Description

Intervention group: In referral session patients history will be taken and intervention's goal will be explained to parents then an informed consent will be taken.First,20% benzocaine local anesthetic gel(Brand: pahl) will be

applied to the subjected area. Right after, Denlase's low level laser (wave length 810 nm, by hand piece therapy(0/78 cross section) 200 mW power, 20 s Radiation time, 5j/cm² density of energy) will be applied to the area for 20 s before injection. This steps will be done once for buccal side and once for palatal side.

Category

Behavior

2

Description

Control group: In referral session patients history will be taken and intervention's goal will be explained to parents then an informed consent will be taken. First, 20% benzocaine local anesthetic gel (Brand: pahl) will be applied to the subjected area. Right after, Denlase's low level laser, which is on off mood will be applied to the area for 20 s before injection. This steps will be done once for buccal side and once for palatal side.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric ward of Dental school of Tehran university of medical science

Full name of responsible person

Bahman Seraj

Street address

Front than Iran atomic energy organization, North Amir abad, Dental school of Tehran university of medical science

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dentistry@tums.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Rezaei

Street address

Front than Iran atomic energy organization , Northern Amir abad, Dental school of Tehran university of

medical science

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Bahman Seraj

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Bahman Seraj

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Bahman Seraj

Position

Associate professor

Latest degree

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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