Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Analgesic effects of pre-infiltration injection topical benzocaine 20% and low-level layser in 6_12 year old children:A randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of superficial anesthesia with 20% benzocaine gel and low power laser on reducing pain perception of infiltrate anesthesia injection in 6-12 years old children

Design

Children referred to the pediatric department of Alborz University of Medical Sciences are divided into two groups of boys and girls. Each case is assigned a number. Then the numbers are written on separate cards and randomly drawn 22 cards between girls and boys. Twenty-three cards were selected from the boys. 45 subjects were selected, one using laser anesthesia and the other with a gel, so the sample size was 45 in each control and intervention group. The study is a double-blind clinical trial.

Settings and conduct

n the control group, the anesthetic injection site is dried and the benzocaine gel applied to the area, and the laser pen is held in place, followed by a short needle injection of lidocaine by the dentist. Drying, placebo cotton swabs are kept in place and prepared by laser power and then anesthesia is injected. The degree of pain perception in both groups is recorded by another person using visual analogue scale scales. And the child and the researcher who record the information are unaware of the anesthetic procedure

Participants/Inclusion and exclusion criteria

Inclusion criteria: Among 6-12 children who need treatment of bilateral maxillary first and second primary molars with infiltrate injection. Exclusion criteria: Among children who have a pacemaker or have systemic problems are excluded from the sample.

Intervention groups

12- to 6-year-old children who received anesthetic injection of 20% benzocaine gel for 30 seconds with cotton swab on dry mucosa (control) / 12- to 6-year-old children who were treated with infrared laser therapy for 60 seconds. (Intervention).

Main outcome variables

Understand injection pain in children, child cooperation with treatment staff.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046178N1**
Registration date: **2020-02-25, 1398/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-25, 1398/12/06**
Update count: **0**

Registration date

2020-02-25, 1398/12/06

Registrant information

Name

maryam jahangiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4448 4289

Email address

jahangiri74mj.mj@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic effects of pre-infiltration injection topical benzocaine 20% and low-level layser in 6_12 year old children:A randomized clinical trial

Public title

analgesic effect of lowlevel laser in pediatric dentistry

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

12-6 years old children who need restoration treatment of first and second maxillary deciduous teeth

Exclusion criteria:

Having pace maker Suffering from systemic disease

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **2**

Analgesic injection for restoration treatment of maxillary both sides

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization Method and Individual Unit - Children will be divided into two groups of boys and girls and each case will be assigned a number and the numbers will be written on separate cards and randomly assigned to the numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

1-In this study for distraction of child and having no impression on VAS(visual analouge scale) keep off laser pen in the part which need no radiation. 2-During study,one of the researchers injects with different ways while the other who records and analyses outcome have no idea about the methods.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Alborz university of medical sience

Street address

Alborz University of Medical Sciences,Azimieh Administrative Town,Taleghani Square,Karaj

City

Karaj

Province

Alborz

Postal code

3198684868

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number

IR.ABZUMS.REC.1398.184

Health conditions studied

1

Description of health condition studied

Dental analgesic

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain injected

Timepoint

Immediately after anesthesia injection

Method of measurement

Visual analoug scale emoji

Secondary outcomes

1

Description

Engage child cooperation

Timepoint

During treatment

Method of measurement

Questionnaire from the therapist

Intervention groups

1

Description

Intervention group: 6 to12 years old children who were given infrared laser therapy with injection of 0.2 watts and energy of 8 joules per point for 60 seconds before

injection. therapy before injection

Category

Treatment - Devices

2

Description

Control group: Children 6 to 12 years of age who have received 20 precent benzocaine gel injection prior to anesthesia.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric ward of Alborz Dental School

Full name of responsible person

Maryam Jahangiri

Street address

Department of Pediatrics, Alborz School of Dentistry, Ketoozadeh St., Golshahr, Iran

City

karaj

Province

Alborz

Postal code

3198684868

Phone

+98 26 3355 5049

Email

jahangiri.m.1995@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Maryam Jahangiri

Street address

Department of Pediatrics, Alborz School of Dentistry, Ketoozadeh St., Golshahr, Karaj ,Iran

City

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Research assistance of Alborz Dental school

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

Karaj University of Medical Sciences

Full name of responsible person

Maryam Jahangiri

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Pediatric ward, Alborz Dental School, Katoozadeh St., Golshahr Ave.

City

Karaj

Province

Alborz

Postal code

3149969415

Phone

+98 26 3355 5049

Email

jahangiri.m.1995@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

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Position

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Phone

0098263355049

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Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

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009826335311614

Email

jahangiri.m.1995@gmail.com

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Patient information such as age, gender, type of treatment received, and method of anesthesia and pain level can be disclosed with ethical and confidentiality guidelines.

When the data will become available and for how long

Access started from 1400

To whom data/document is available

Anyone interested in research or work in the field.

Under which criteria data/document could be used

1.There is a justified reason for obtaining the documentation. 2. Have a university degree or research related job

From where data/document is obtainable

Send an email to jahangiri74mj.mj@gmail.com

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

After submitting the email containing the request, the request will be shared with other project partners and after obtaining their consent, the administrative steps involved in communicating with the Alborz University of Medical Sciences will be made available to applicants if the university permits.

Comments