

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of effectiveness of using "external cold and vibration" in contrast with control group on amount of pain caused by infiltration injection in 6-12 years old children: randomized clinical trial

Protocol summary

Study aim

Evaluation of effectiveness of using external cold and vibration in contrast with topical anesthesia in amount of pain perceived by children aged between 6-12 years during infiltration technique injection

Design

A randomized, double-blind clinical trial, with control group

Settings and conduct

This study will be held in faculty of dentistry, Isfahan university of medical sciences. The child's mouth is divided into two parts and it is randomly determined to use vibration and cold on one side and topical anesthesia gel on the other side. Participants will not know whether they participate in case or control group. Participants will then be assigned with identifiers, generated with an online number generator software, therefor outcome assessors and the manuscript writers will be blind to the identity of participants in both case and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria for this study are children aged 6-12 years who refer to special clinics of the School of Dentistry of Isfahan University of Medical Sciences and need deep restoration of D or E teeth on both sides of the maxilla and want to participate in the study.

Intervention groups

The child's mouth is divided into two parts (split mouth) and it is randomly determined to use vibration and cold on one side and on the other side only anesthetic gel.

Main outcome variables

Pulse rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111219008458N3**

Registration date: **2021-08-03, 1400/05/12**

Registration timing: **prospective**

Last update: **2021-08-03, 1400/05/12**

Update count: **0**

Registration date

2021-08-03, 1400/05/12

Registrant information

Name

Sanaz Ziaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-20, 1400/05/29

Expected recruitment end date

2021-10-21, 1400/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of using "external cold and vibration" in contrast with control group on amount of pain caused by infiltration injection in 6-12 years old

children: randomized clinical trial

Public title
Effect of "External Cold and Vibration" on Maxilla Infiltration injection

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children referred to the School of Dentistry of Isfahan University of Medical Sciences Be mentally and physically healthy They do not take analgesics or sedatives Be positive or completely positive in terms of Frankl division Have no previous dental history Do not have toothache when referred Need deep restoration of D or E teeth on both sides of the maxilla Willing to participate in the study
Exclusion criteria:

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Apply external cold and vibration during injection in one side of the mouth and apply topical anesthetic gel for the other side

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Random Sampling: Simple randomization using google's online coin flipper. First, each group will be assigned to a coin flip result. Thereafter, a coin flip will be performed using google's online coin flipper, for each individual, and it will be decided whether the participant is in the Case or Control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will not know whether they participate in case or control group. Participants will then be assigned with identifiers, generated with an online number generator software (numbargenerator.org). Therefor, the outcome assessors, and the manuscript writers will be blind to the identity of participants in both Case and Control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib street

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Postal code

8174673461

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.835

Health conditions studied

1

Description of health condition studied

Pain When Injecting Maxillary Infiltration

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart rate during infiltration injection on maxillary teeth

Timepoint

5 minutes before injection, during injection, 5 minutes after injection

Method of measurement

Pulse Oxymeter

Secondary outcomes

empty

Intervention groups

1

Description

Hold the Buzzy(external cold and vibration) on the mucosa of the injection site for two minutes and inject the anesthetic (1.8 ml 2% lidocaine with 1: 100000 epinephrine using a 27 gauge and short needle).The device should be in place while injecting

Category

Treatment - Devices

2

Description

Control group: Benzocaine 20% Dentotix (North Carolina) topical anesthetic gel is applied and injected for 30 seconds.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzal dental clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Sanaz Ziaei

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not 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

Evaluation of external cold and vibration in contrast with topical anesthesia gel in amount of pain perceived by children during infiltration injection

When the data will become available and for how long

Not decided

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Not decided

From where data/document is obtainable

Not decided

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

Not decided

Comments