

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of effectiveness of using “external cold and vibration” and “cold” on amount of pain caused by maxillary infiltration in 6-12 year-old children

Protocol summary

Study aim

Considering the importance of pain and stress control in pediatric we decided to improve pain management techniques and increase treatment satisfaction for children

Design

Randomized clinical trial, crossover control, double blind, on 30 patients.

Settings and conduct

The site of this study is doctor mehdi jafarzade clinic. After applying BUZZY, we calculate the amount of pain felt with two scales, Wong-Baker and FLACC. we write down pulse rate before, during and after the injection. To blind the child, we put the device off his face in the control session. We use a pulse oximeter to measure heart rate.

Participants/Inclusion and exclusion criteria

Children 6-12 years old are physically and mentally healthy, have no underlying disease, do not take painkillers or sedatives. Be positive or completely positive about frankl's behavioral classification. Have no previous history of dental treatment and toothache at the time of visit, require deep D or E teeth restoration on both sides of the maxilla. Children with chronic illness, mental problems, behavioral problems, congenital disorders, hearing and speech disorders, if the area to be implanted has pathology or inflammation, non-working children will be excluded from the study.

Intervention groups

The Buzzy places on the skin of the injection site and holds it for two minutes. The dentist then applies 20% benzocaine surface anesthesia gel to the mucosa of the injection site with an applicator and performs the infiltration anesthesia for one minute after 30 seconds. In the control session, only the superficial anesthesia gel is used.

Main outcome variables

Amount of felt pain, heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210815052196N1**

Registration date: **2021-09-04, 1400/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-04, 1400/06/13**

Update count: **0**

Registration date

2021-09-04, 1400/06/13

Registrant information

Name

Fateme Shadmanfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 9123

Email address

fatemeshd@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-25, 1400/06/03

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of effectiveness of using “external cold and vibration” and “cold” on amount of pain caused by maxillary infiltration in 6-12 year-old children

Public title

Effect of cold and external vibration in local anesthesia

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Children who are physically and mentally healthy, they have no underlying disease they are not currently taking painkillers or sedatives Children should be positive or completely positive about Frankl's behavioral classification during the dental examination he child should have no history of previous dental treatment and toothache at the time of referral they require deep D or E tooth restorations on both sides of the maxilla they are willing to participate in the study

Exclusion criteria:

Have a history of hospitalization due to dental surgery children with chronic illnesses (such as asthma, allergies, diabetes, sickle cell disease, cystic fibrosis, dermatitis) children with behavioral problems (such as autism, ADHD, learning disabilities) patients with mental health problems, patients Congenital disorders, hearing and speech disorders are also not included in the study The child will be excluded from the study if the area to be implanted has pathology or if there is inflammation at the injection site non-working children will not participate in the study.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

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

Each child has an intervention session and a control session, each session being performed on one side of the jaw

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is done by sealing the envelope. The randomization unit is individual. There are two envelopes, one with the word buzzy and the other with the word control. We ask the child to choose an envelope at the beginning of the session. The package that will be chosen will be the treatment method in the

first session.

Blinding (investigator's opinion)

Double blinded

Blinding description

The analyzer does not know the data related to intervention and control. Also, in the control session for blinding the participant, the device is placed off on the child's face.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St, Esfahan

City

Esfahan

Province

Isfahan

Postal code

7346181746

Approval date

2021-08-22, 1400/05/31

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.220

Health conditions studied**1****Description of health condition studied**

A child has deep caries in the maxillary D and E teeth that requires local anesthesia.

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes**1****Description**

Pain index

Timepoint

Measure of pain index immediately after injection

Method of measurement

Wong-baker index, FLACC index

2

Description

Heart rate

Timepoint

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

Method of measurement

Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The parent places the Buzzy on the skin of the injection site and holds it for two minutes. The dentist applies surface anesthesia gel to the mucosa of the injection site with an ear cleaner, and after 30 seconds of injection, performs the infiltration anesthesia for one minute. The device should be in place during the application of the superficial anesthetic gel and the injection.

Category

Treatment - Devices

2

Description

Control group: only cold and surface anesthesia gel are used. To blind the baby, we put the Buzzy on the baby's face without turning on the vibration and cold wings, and after two minutes, the surface anesthetic gel is applied by the ear cleaner for 30 seconds and the injection is done.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Doctor mehdi jafarzade clinic

Full name of responsible person

Doctor mehdi jafarzade

Street address

Third floor, Sepehr Building, corner of Hezar Jerib, Darvase Shiraz, Esfahan.

City

Esfahan

Province

Isfahan

Postal code

8168953381

Phone

+98 31 3669 8825

Email

Mejsamani@yahoo.co.uk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh haghjoy javanmard

Street address

Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St, Esfahan.

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 7898

Email

research@mui.ac.ir

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

Dr Reyhane Faghihian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

9th floor, Block 4, Doctors Building, Aref St., Third

Moshtaq, Esfahan.

City

Esfahan

Province

Isfahan

Postal code

8158184959

Phone

+98 31 3263 8163

Email

Reyhane.fgh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Reyhane Faghihian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

9th floor, Block 4, Doctors Building, Aref St., Third
Moshtaq, Esfahan.

City

Esfahan

Province

Isfahan

Postal code

8158184959

Phone

+98 31 3263 8163

Email

Reyhane.fgh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Reyhane Faghihian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

9th floor, Block 4, Doctors Building, Aref St., Third
Moshtaq, Esfahan.

City

Esfahan

Province

Isfahan

Postal code

8158184959

Phone

+98 31 3263 8163

Email

reyhane.fgh@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

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

Age and gender, Frankel classification, fear score,
children's heart rate after non-identification

When the data will become available and for how long

Access starts one month after publication

To whom data/document is available

General dentists and pediatric dentists , researchers
working in academic institutions can apply for it.

Under which criteria data/document could be used

The use of data for systematic review and meta analysis
will be allowed.

From where data/document is obtainable

Dr. Reyhane Faghihian reyhane.fgh@gmail.com Fateme
shadmanfar. fatemeshd@yahoo.com

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

The applicant must submit their application via email.
The email must state the reason for the request and the
use of it. Data will be sent up to one month after the
request is submitted.

Comments