Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Pain and Anxiety Associated with Digital and Conventional Local Anesthesia Injection in Maxillary Primary Canine Teeth in Children Aged 5 to 9 Years

Protocol summary

Study aim

To investigate and compare the anxiety and pain levels associated with digital and conventional local anesthesia injections in the maxillary primary canine teeth of children aged 5 to 9 years. The study will assess heart rate, the Wong-Baker, FACES with results analyzed separately for boys and girls

Design

42 children randomized into groups A & B for alternating digital/conventional anesthesia. Selection via sealed envelopes by blinded secretary. Visits spaced 7-14 days apart. Benzocaine gel pre-injection, both methods use 1:80000 lidocaine. Pain/anxiety assessed by Wong-Baker FACES and FLACC scales.

Settings and conduct

The study will be conducted in the Pediatric Dentistry Department of Kerman Dental School (1404-1405). Participants will be randomly divided into two groups. The department secretary (blinded) will select the treatment card, and the resident (blinded) will perform the injection. The second visit will be conducted 7 to 14 days later by the same resident. Parents will provide consent before treatment.

Participants/Inclusion and exclusion criteria

A study will be conducted on 42 children aged 5 to 9 years visiting the pediatric dentistry department of Kerman Dental School during the academic year 1404–1405. Inclusion criteria: Need for anesthesia in both primary maxillary canines, ability to communicate, parental consent, and Frankl behavior rating of 3 or 4. Exclusion criteria: Consumption of analgesics in the past 48 hours, previous dental treatment history, behavioral problems, systemic diseases, or contraindications for local anesthesia.

Intervention groups

Before injection, benzocaine gel is applied for 1-2 minutes. For digital anesthesia, a 9mm gauge 30 needle is used, and for conventional anesthesia, a 16mm gauge 30 needle is used. Both methods are performed with a lidocaine solution containing 1:80000 epinephrine.

Main outcome variables

Anxiety and pain levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260224068935N1**
Registration date: **2026-03-22, 1405/01/02**
Registration timing: **prospective**

Last update: **2026-03-22, 1405/01/02**
Update count: **0**

Registration date

2026-03-22, 1405/01/02

Registrant information

Name

mohadese saeedi sarvestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 213 1306

Email address

dr.mohadesesaeedi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-05-05, 1405/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Pain and Anxiety Associated with Digital and Conventional Local Anesthesia Injection in Maxillary Primary Canine Teeth in Children Aged 5 to 9 Years

Public title
Comparison of pain and anxiety during digital and conventional anesthesia in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
children between 5 and 9 years who need to inject anesthesia in the maxillary canine teeth on both sides of the arch . they can communicate mentally . parental consent to the project patients with rating of frank's behavior 3 and 4
Exclusion criteria:
Children who have used painkillers within 48 hours before treatment. Children with previous dental experience. Children with a history of significant behavioral management problems are excluded from the study. Have a systemic disease. Have contraindications for the use of local anesthetics.
Age
From **5 years** old to **9 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participants are individually assigned to one of two treatment groups (A and B) using simple randomization with sealed envelopes; for this purpose, 42 cards (21 for treatment A and 21 for treatment B) were prepared, placed in sealed envelopes, and put into a box. Subsequently, the department secretary, unaware of the envelopes' contents, randomly selects one envelope per participant without replacement, and the corresponding treatment is administered by a pediatric resident in the first visit (conventional for A, digital for B), with the second visit (digital for A, conventional for B) occurring 7 to 14 days later by the same resident; this process ensures allocation concealment.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding has been implemented to prevent potential bias in participant responses. Participants will be unaware of which type of anesthesia intervention (digital or conventional) they are receiving during each visit. However, it should be noted that the resident responsible for administering the injections and assessing outcomes (pain and anxiety) is aware of the patients' treatment group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Kerman - Islamic republic boulevard - the end of Shafa road - the faculty of dentistry of kerman university of medical sciences
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2025-11-02, 1404/08/11
Ethics committee reference number
IR.KMU.REC.1404.457

Health conditions studied

1

Description of health condition studied
Pain from Local Anesthetic Injections
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

2

Description of health condition studied
Anxiety from Local Anesthetic Injections
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
heart rate
Timepoint
during injection
Method of measurement
pulls oximeter

2

Description
pain
Timepoint
during injection
Method of measurement
according to Wong-baker scale

3

Description
physical reaction
Timepoint
during injection
Method of measurement
FLACC pain scale: Face (F): This refers to facial expressions. It includes observing muscle tension, frowning, or whether the eyes or mouth are open or closed. Legs (L): This category assesses the position and movement of the legs. It looks for whether the legs are relaxed, stiff, or if there are any involuntary movements like kicking or thrashing. Activity (A): This evaluates the child's overall activity level. It notes if they are calm, restless, or if their body is rigid. Cry (C): This focuses on the sound the person is making. It ranges from no crying to moaning or loud crying. Consolability (C): This measures how easily the person can be comforted. It assesses whether they can be soothed with touch or reassurance.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Digital anesthesia is first applied before the injection of local anesthetic using a benzocaine gel for 1-2 minutes on the previously dried mucosa. For digital anesthesia, the Sleeper One 5 device from Dental Hitec, French, and a short gauge 16 needle are used, following the manufacturer’s instructions. The anesthetic solution used is lidocaine with epinephrine 1:80,000.
Category
Treatment - Other

2

Description
Intervention group: first applied before the injection of local anesthetic using a benzocaine gel for 1-2 minutes on the previously dried mucosa.For conventional anesthesia, gauge 30 needles of 16mm length are used. The anesthetic solution used in both methods is lidocaine with epinephrine 1:80,000
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of pediatrics at faculty of dentistry the university of medical sciences of Kerman
Full name of responsible person
Elham- Faroukh-Gisvar
Street address
Kerman - Islamic republic boulevard - the end of Shafa road - the faculty of dentistry of kerman university of medical sciences
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 917 213 1306
Email
Faroukh@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hamid Sharifi
Street address
Kerman - Islamic republic boulevard - the end of Shafa road - the faculty of dentistry of kerman university of medical sciences
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3211 9021
Email
sharifihami@gmail.com
Grant name
Research department of kerman university of medical

sciences

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Elham Faroukh-gisvar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Kerman - Islamic republic boulevard - the end of Shafa road - the faculty of dentistry of kerman university of medical sciences

City

kerman

Province

Kerman

Postal code

7616913555

Phone

+98 917 213 1306

Email

Faroukh@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Elham Faroukh gisvar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Kerman - Islamic republic boulevard - the end of Shafa road - the faculty of dentistry of kerman university of medical sciences

City

kerman

Province

Kerman

Postal code

7616913555

Phone

+98 917 213 1306

Email

Faroukh@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Elham Faroukh-gisvar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Kerman - Islamic republic boulevard - the end of Shafa road - the faculty of dentistry of kerman university of medical sciences

City

kerman

Province

Kerman

Postal code

7616913555

Phone

+98 917 213 1306

Email

Faroukh@kmu.ac.ir

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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how

long

starting 12 months after publication

To whom data/document is available

The data will be available to all requesters, including researchers and administrators.

Under which criteria data/document could be used

Data can be used solely for meta-analysis studies.

From where data/document is obtainable

Applicants should email the corresponding author.

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

Applicants should solely email the corresponding author, providing the title of their meta-analysis study and, if registered in PROSPERO, the PROSPERO code.

Comments