

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Pain and Anxiety in Children Using Conventional Syringe and Computer-Controlled Local Anesthetic Delivery System during Inferior Alveolar Nerve Block

Protocol summary

Study aim

Comparison of pain levels during local anesthesia injection using conventional and digital methods. Comparison of child anxiety before and during the injection with conventional and digital methods.

Design

A randomized controlled clinical trial with a crossover design involving 25 patients. In this study, the randomization process is performed using blocked randomization and follows a split-mouth crossover design. In this study, blinding is not feasible due to the nature of the instruments used.

Settings and conduct

For this study, a sample of 50 children aged 7 to 11 years requiring bilateral inferior alveolar nerve block (IANB) was selected from patients visiting the Pediatric Dentistry Department of Shahid Sadoughi Dental School in Yazd. For each participant, standard-sized sheets with printed codes "A" or "B" were prepared. These codes corresponded to the two types of interventions as follows: Group A: IANB local anesthesia injection using a digital syringe Group B: IANB local anesthesia injection using the conventional syringe method

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy and cooperative children (ASA I or II; Frankl ratings 3 and 4), aged 7 to 11 years, who require bilateral pulpotomy treatment in the mandibular primary molars. No allergy to local anesthetic agents and no previous unpleasant dental experience. Additionally, the exclusion criterion is the withdrawal of the child or parents from participation in the study.

Intervention groups

Group A: Inferior Alveolar Nerve Block local anesthesia injection using a digital syringe Group B: Inferior Alveolar Nerve Block local anesthesia injection using the conventional syringe method

Main outcome variables

Objective pain intensity; subjective (perceived) pain intensity; behavioral anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140601017935N10**

Registration date: **2026-06-16, 1405/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2026-06-16, 1405/03/26**

Update count: **0**

Registration date

2026-06-16, 1405/03/26

Registrant information

Name

Zahra Bahrololoomi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences-Yazd

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-07-23, 1405/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pain and Anxiety in Children Using Conventional Syringe and Computer-Controlled Local Anesthetic Delivery System during Inferior Alveolar Nerve Block

Public title

Comparison of pain in children using conventional syringe and digital syringe

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy and (ASA I or II), aged 7 to 11 years, who require bilateral pulpotomy treatment in the mandibular primary molars. No allergy to local anesthetic agents No previous unpleasant dental experience Cooperative children (Frankl ratings 3 and 4)

Exclusion criteria:

Withdrawal of the child or parents from participation in the study

Age

From **7 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using the blocked randomization allocation method. A random sequence was generated using PASS 2021 software based on block randomization. In total, twelve 4-member blocks were created to ensure the equal allocation of 50 participants into two groups (A: intervention, B: control).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Imam Reza Boulevard

City

Yazd

Province

Yazd

Postal code

8915874391

Approval date

2026-01-12, 1404/10/22

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1404.067

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

Patient with reversible pulpitis in a mandibular primary molar

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

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

The outcome variable of anesthesia success on the WB scale is considered a successful treatment with scores of zero and two and a failure with scores of four to ten. Similarly, FBRs grades three and four are considered a successful treatment and grades one and two are considered a failure.

Timepoint

In the same treatment session

Method of measurement

To determine the level of pain during pulp treatment, we use two objective and subjective indicators. The Wong-Baker FACES Pain Rating Scale; WBS, which is a set of six facial images, is used to subjectively measure pain. Each child is asked to select a face from the WBS that represents their level of pain. The Face Leg Activity Cry Consolability (FLACC) scale is an objective pain measurement index that includes 5 sections: facial expression, leg position, child activity, crying, and child consolability. Each section is assigned a score between 0 and 2, and the total score is calculated. To measure the level of pain based on the FLACC index, it is performed by another assistant who is independent of the study and its results.

Secondary outcomes

empty

Intervention groups

1

Description

Group A :An inferior alveolar nerve block injection will be administered using a digital syringe (Computer-Controlled Local Anesthetic Delivery System). Heart rate and oxygen saturation (SpO₂) will be recorded before and after the injection, and the child's pain and anxiety levels will be assessed using standardized assessment tools.

Category

Treatment - Devices

2

Description

Group B :An inferior alveolar nerve block injection will be administered using a conventional dental syringe. Heart rate and oxygen saturation (SpO₂) will be recorded before and after the injection, and the child's pain and

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatric Dentistry, School of Dentistry, Shahid Sadoughi University of Medical Scienc

Full name of responsible person

Zahra Sameii

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Karimi Mehran

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Imam Reza Educational Complex ,Vice-Chancellery for Research and Technology, Daneshjoo Boulevard, Imam Hossein Square

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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

Yazd University of Medical Sciences

Proportion provided by this source

50

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

Yazd University of Medical Sciences

Full name of responsible person

Zahra Sameii

Position

Pediatric Dentistry Resident

Latest degree

Medical doctor

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