Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone
+98 35 1624 0691

Email address
zbahrololoom@ssu.ac.ir

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 (SpO_2) 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 (SpO_2) 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
Street address
Farhang 2 , Mehravaran
City
Yazd
Province
Yazd
Postal code
8915846793
Phone
+98 35 3625 6975
Email
z.sameie1998@gamil.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Karimi Mehran
Street address
Imam Reza Educational Complex ,Vice-Chancellery for Research and Technology, Daneshjoo Boulevard, Imam Hossein Square
City
Yazd
Province
Yazd
Postal code
8916188637
Phone
+98 913 151 9608
Email
mehrankarimi@ssu.ac.ir
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
Dentistry
Street address
Farhang 2 , Mehravaran
City
Yazd
Province
Yazd
Postal code
8915846793
Phone
+98 35 3625 6975
Email
z.sameie1998@gmail.com

Person responsible for scientific 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
Dentistry
Street address
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City
Yazd
Province
Yazd
Postal code
8915846793
Phone
+98 35 3625 6975
Email
z.sameie1998@gmail.com

Person responsible for updating data

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
Dentistry
Street address
Farhang 2 , Mehravaran
City
Yazd
Province
Yazd
Postal code
8915846793
Phone
+98 35 3625 6975
Email
z.sameie1998@gmail.com

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