Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Randomized split-mouth clinical trial comparing pain, anxiety and disruptive behavior during inferior alveolar nerve block using traditional syringe and digital.

Protocol summary

Study aim

to determine the relationship between the levels of pain, anxiety, and disruptive behavior in children during inferior alveolar nerve block injection using two methods: traditional and digital.

Design

A randomized, double-blind, controlled clinical trial with a cross-over design involving 15 patients.

Settings and conduct

Children aged 5–8 years from Qazvin School of Dentistry (pediatric department) will be randomly assigned to two groups. Each group will receive both traditional and digital injections one week apart, in reverse order.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 5 to 8 years, provided that their developmental stage is consistent with their chronological age; children classified as American Society of Anesthesiologists (ASA) physical status I; children requiring bilateral mandibular nerve blocks; and children with no prior history of receiving dental local anesthesia before the study. Exclusion criteria: patients with a history of hypersensitivity to local anesthetics; patients with any mental or physical condition that might interfere with the treatment procedure.

Intervention groups

Group I: Traditional method in first session → CCLAD (DentaPen) in second session. Group II: CCLAD in first session → Traditional method in second session. Procedure (per patient per session): Tell-Show-Do technique. Dry injection site with cotton swab for 60 seconds. Apply procaine gel for 2 minutes. Use 27-gauge, 25 mm needle. Inject 1.5–1.8 mL of 2% lidocaine with 1:80,000 epinephrine after contacting bone. Measurements (at three time points): Pulse rate, blood pressure, FLACC, Venham anxiety scale (VPTm), and Wong–Baker Faces Pain Rating Scale (WBF).

Main outcome variables

Objective assessment: FLACC scale; Subjective assessment: Wong–Baker Faces Pain Rating Scale; heart rate; blood oxygen saturation (SpO_2); Venham anxiety scale (VPTm).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260419069108N1**
Registration date: **2026-05-13, 1405/02/23**
Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**
Update count: **0**

Registration date

2026-05-13, 1405/02/23

Registrant information

Name

Razieh Hosseininavaz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-03, 1405/04/12

Expected recruitment end date

2026-11-03, 1405/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized split-mouth clinical trial comparing pain, anxiety and disruptive behavior during inferior alveolar nerve block using traditional syringe and digital.

Public title

clinical trial comparing pain, anxiety and disruptive behavior during inferior alveolar nerve block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children aged 5 to 8 years, provided that their developmental stage is consistent with their chronological age children classified as American Society of Anesthesiologists (ASA) physical status I children requiring bilateral mandibular nerve blocks children with no prior history of receiving dental local anesthesia before the study

Exclusion criteria:

patients with a history of hypersensitivity to local anesthetics patients with any mental or physical condition that might interfere with the treatment procedure.

Age

From **5 years** old to **8 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 patient will receive different interventions on each side of the mouth.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using sealed, opaque envelopes containing an equal number of intervention (digital method) and control (traditional method) allocations will be employed. The envelopes will be provided to a ward nurse who is not involved in any subsequent part of the study. Each time, the nurse will draw one envelope to determine whether the patient will receive the intervention or control.

Blinding (investigator's opinion)

Double blinded

Blinding description

he injection technique for the block will be performed in such a way that the child (participant) cannot see the type of syringe used. Furthermore, the group allocation results for each subject will be provided to the statistical analyst in the form of numerical codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd.

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2026-02-23, 1404/12/04

Ethics committee reference number

IR.QUMS.REC.1404.444

Health conditions studied

1

Description of health condition studied

injection in pediatric dentistry

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Objective assessment of pain

Timepoint

during inferior alveolar nerve block injection

Method of measurement

Face, Legs, Activity, Cry, Consolability (FLACC) scale

2

Description

Subjective assessment of pain

Timepoint

after inferior block injection

Method of measurement
Wong-baker scale

3

Description
Pulse
Timepoint
before and during inferior alveolar black
Method of measurement
pulse oximeter

4

Description
Oxygen saturation of blood
Timepoint
before and during inferior alveolar black
Method of measurement
pulse oximeter

5

Description
anxiety
Timepoint
after inferior alveolar black injection
Method of measurement
Venham anxiety index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Here is the scientific English translation of the "Intervention Group" text you provided, without additional explanations:**Intervention group:** Informed consent will first be obtained from the patient. A complete medical and dental history will be taken in writing from the parents. Subsequently, a full patient examination, including clinical and radiographic evaluation, will be performed. The clinical examination will be conducted first, and a diagnosis of dental caries in tooth D or E will be made. To confirm the diagnosis and the need for pulp therapy, a periapical radiograph will be taken. The treatment plan—either pulpotomy or pulpectomy—and the need for bilateral mandibular nerve block will be established. It should be noted that in each child, the tooth type (D or E) and the treatment plan (pulpotomy or pulpectomy) will be exactly the same on both sides of the mouth.1) The tell-show-do technique will first be performed for the patient.2) A cotton roll will be placed on the anesthesia injection site for 60 seconds to completely dry the area.3) Proccaine gel will be applied to the anesthesia site for 2 minutes.4) An appropriate needle (27-gauge, 25 mm length) will then be selected.5) The needle will be inserted into the tissue using the Dentapen device. After passing through the mucosa and contacting the bone, 1.5 to 1.8 mL of local anesthetic solution—lidocaine 2% with epinephrine 1:80,000—will be injected.
Category
Treatment - Other

2

Description
Control group: Here is the scientific English translation of your text, as requested without explanations:"Informed consent will first be obtained from the patient. A complete medical and dental history will be taken in writing from the parents. Subsequently, a full patient examination, including clinical and radiographic evaluation, will be performed. The clinical examination will be conducted first, and a diagnosis of dental caries in tooth D or E will be made. To confirm the diagnosis and the need for pulp therapy, a periapical radiograph will be taken. The treatment plan—either pulpotomy or pulpectomy—and the need for bilateral mandibular nerve block will be established. It should be noted that in each child, the tooth type (D or E) and the treatment plan (pulpotomy or pulpectomy) will be exactly the same on both sides of the mouth.1) The tell-show-do technique will first be performed for the patient.2) A cotton roll will be placed on the anesthesia injection site for 60 seconds to completely dry the area.3) Proccaine gel will be applied to the anesthesia site for 2 minutes.4) An appropriate needle (27-gauge, 25 mm length) will then be selected.5) The needle will be inserted into the tissue using a traditional syringe. After passing through the mucosa and contacting the bone, 1.5 to 1.8 mL of local anesthetic solution—lidocaine 2% with epinephrine 1:80,000—will be injected."
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin university of medical sciences
Full name of responsible person
Razie Sadat Hosseininavaz
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Qazvin 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
Other

Person responsible for general inquiries

Contact
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Razie Sadat Hosseininavaz
Position
Resident
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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