

# Effectiveness of the Buzzy device in decreasing pain during intraoral injection in children

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<b>Registration date</b> 22/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
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## Plain English summary of protocol

### Background and study aims

Evidence supports combining extraoral vibration and cooling to reduce pain during intraoral local anesthesia. This study aimed to evaluate the effectiveness of external cooling and vibration using the Buzzy device in reducing intraoral injection pain during inferior alveolar nerve block (IANB) in children aged 6 to 10 years. The study compared four intervention approaches: the conventional tell-show-do (TSD) technique, vibration alone, cooling alone, and a combined vibration-cooling method.

### Who can participate?

Children aged 6–10 years requiring local anesthesia for mandibular posterior teeth

### What does the study involve?

100 participants were randomly divided into four groups (n = 25):

- Group 1: control group, TSD technique.
- Group 2: vibration group.
- Group 3: cooling group.
- Group 4: BUZZY group.

### What are the possible benefits and risks of participating?

Possible benefits are: Performing non-urgent dental treatment in the mandibular arch, such as pulpotomy, serial extraction, and pulpectomy.

Possible risk is: IANB will be painful if the device is not effective.

### Where is the study run from?

Damascus University (Syria)

### When is the study starting and how long is it expected to run for?

March 2024 and July 2025

### Who is funding the study?

Damascus University (Syria)

Who is the main contact?

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## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Effectiveness of external cooling and vibration using the Buzzy device in decreasing during inferior alveolar nerve block pain in children aged 6 to 10 years: A randomized controlled clinical trial

### Study objectives

This study aimed to evaluate the effectiveness of external cooling and vibration using the Buzzy device in reducing intraoral injection pain during inferior alveolar nerve block (IANB) in children aged 6 to 10 years.

### Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 03/04/2024, The Biomedical Research Ethics Committee (Mazzeh, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: 556

## Study design

Double-blind quadruple-arm parallel-group randomized active-controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Pain and anxiety

## Interventions

Participants were randomly assigned to one of four groups using an online randomization tool, [www.randomizer.org](http://www.randomizer.org), with allocation generated in four equal sets across a number range of 1–100.

Upon seating in the dental chair, all participants had a pulse oximeter placed on their index finger for physiological monitoring. The control group received conventional TSD behavioral management. For the vibration group, the Buzzy device (Buzzy® Mini Healthcare, Pain Care Labs, Georgia, United States) was applied to the injection site on the cheek for one minute with vibration-activated but cooling wings inactivated. The cooling group received the Buzzy device with pre-cooled wings, with the vibration component disabled. It was applied to the cheek for one minute. In the combined intervention group, the Buzzy device with activated vibration and pre-cooled wings was similarly positioned for one minute before injection. The device's ice wings were pre-cooled to 0°C, while its vibration mechanism operated at a fixed frequency of 100 Hz. Following initial interventions, participants were asked to select a face from the FIS while baseline pulse oximeter readings were recorded. The injection site was isolated and dried, followed by topical application of 20% benzocaine (Iolite, Dharma Research Inc., Florida, United States) for two minutes. IANB was then administered using a 27-gauge, 21-mm needle (Disposable Dental Needle, Shanghai Dochem Industries Co., Ltd., Shanghai, China) containing 1.8 mL of 2% lidocaine with 1:80,000 epinephrine (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam, Korea), delivered via a dental carpule syringe (Dental carpule syringe, Dental Laboratorio, china). The injection point was determined at the occlusal plane level of the contralateral primary teeth. The syringe was advanced toward the mandibular foramen until bone contact was achieved. Slow administration of 1 mL anesthetic solution over one minute was performed. The FLACC behavioral pain scale was video-recorded during the injection process. Post-injection, pulse rate measurement was repeated, and participants completed both the Wong-Baker FACES Pain Rating Scale and FIS to assess immediate pain and anxiety responses.

## Intervention Type

Device

## Phase

Not Applicable

**Drug/device/biological/vaccine name(s)**

The Buzzy device (Buzzy® Mini Healthcare, Pain Care Labs, Georgia, United States)

**Primary outcome(s)**

1. Pulse rate was objectively measured as an indicator of dental pain and anxiety using a finger pulse oximeter (Alpha, Prolinx GmbH, Düsseldorf, Germany) at baseline (t0) prior to any intervention, and immediately following inferior alveolar nerve block (IANB) administration (t1)
2. Procedural pain during IANB injection was measured using the Face, Legs, Activity, Cry, and Consolability (FLACC) Behavioral Pain Assessment Scale at t1. Video recordings of each procedure were obtained to enable standardized, retrospective scoring by trained outcome assessors.
3. Participants' subjective pain perception was assessed using the Wong-Baker FACES Pain Rating Scale (WBFPS) at t1. Children were instructed to select the facial expression that best represented their pain experience during the procedure, with scores ranging from 0, no pain, to 10, worst pain imaginable.

**Key secondary outcome(s)**

Subjective anxiety levels were measured using the Facial Image Scale (FIS), a 5-point pictorial scale featuring facial expressions ranging from very happy (score = 1) to very fearful (score = 5). Children were instructed to select the face that best represented their emotional state at pre-injection, baseline (t0), and post-IANB administration (t1).

**Completion date**

10/07/2025

**Eligibility****Key inclusion criteria**

1. Children aged 6–10 years
2. Children requiring local anesthesia for mandibular posterior teeth
3. Children exhibiting positive behavior, rated as "positive" or "definitely positive" on the Frankl Behavior Scale

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

10 years

**Sex**

All

**Total final enrolment**

100

**Key exclusion criteria**

1. Children with systemic diseases or a known allergy to local anesthesia or its components
2. Children who refuse to wear the study device
3. Children with a previous history of dental injections

**Date of first enrolment**

09/05/2025

**Date of final enrolment**

04/07/2025

**Locations****Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

Mazzeh

Damascus

Syria

Nil

**Sponsor information****Organisation**

Damascus University

**ROR**

<https://ror.org/03m098d13>

**Funder(s)****Funder type**

University/education

**Funder Name**

Damascus University

**Alternative Name(s)**

University of Damascus, , DU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Syria

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from [mawia95.karkoutly@damascusuniversity.edu.sy](mailto:mawia95.karkoutly@damascusuniversity.edu.sy), [mawiamaherkarkoutly@hotmail.com](mailto:mawiamaherkarkoutly@hotmail.com)

The type of data that will be shared: Not currently known

Timing for availability: Upon a reasonable request

Whether consent from participants was required and obtained: Informed consent was obtained

**IPD sharing plan summary**

Available on request