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

Submission date
18/07/2025

Recruitment status
No longer recruiting

Registration date
22/07/2025

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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, 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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The Buzzy device (Buzzy® Mini Healthcare, Pain Care Labs, Georgia, United States)

Primary outcome measure
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.

Secondary outcome measures
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).

Overall study start date
03/03/2024

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

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
100

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
Nill

Sponsor information

Organisation
Damascus University

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University/education

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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

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/09/2025

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, 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