

# Comparative efficacy of various topical anesthetics during dental injection in pediatric patients

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<b>Registration date</b> 07/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Lidocaine is a rapid onset amine–amide anesthetic. In addition, it is widely acceptable due to its potency and low toxicity. Lidocaine gel, to date, is the gold standard topical anesthetic. However, benzocaine was superior to lignocaine gel in relieving pain during IANB, and it was the most favorite topical anesthetic among dental practitioners. 8% lidocaine gel was superior to 2% lidocaine gel in topical ocular anesthesia during intravitreal injection, and higher lidocaine concentrations do not cause toxicity. However, 8% lidocaine gel effectiveness in alleviating pain during dental injections has not been extensively studied. A eutectic mixture of local anesthetics (EMLA) is a topical cream containing a combination of 2.5% lidocaine and 2.5% prilocaine, which has gained popularity in recent years. EMLA is a potent topical anesthetic cream that belongs to the amide group of local anesthetics. In addition, it has been used on oral mucosa to reduce pain during dental treatments such as gingival probing, periodontal scaling, root planning, and other minor dental treatments. However, research comparing EMLA cream and lidocaine gel was not conclusive. In addition, studies comparing various topical anesthetics during IANB administration are scarce. Hence, this study aimed to evaluate the efficacy of 5% EMLA cream and 8% lidocaine gel in reducing pain during IANB compared with 20% Benzocaine in children aged 6-10 years.

### Who can participate?

Children aged 6-10 years requiring non-urgent dental treatment under IANB.

### What does the study involve?

Patients were randomized using the randomization online software <https://www.randomizer.org/>. A simple randomization method was applied to randomly allocate patients into 3 groups in a ratio of 1:1:1.

This was a triple-blind trial where patients, clinicians, and data analysts were blinded to which experimental arms patients were allocated.

The participants were randomly assigned into 3 groups. The first group received 20% benzocaine gel (control group). The second group received 8% lidocaine gel. The third group received 5% EMLA cream. Each topical anesthetic was applied in an amount of 0.3 mL using a cotton swab for 2 minutes at the site of IANB administration after drying the mucosa. A conventional IANB was

performed using a dental carpule syringe (Dental carpule syringe, Dental Laboratorio) and a 27-gauge x 3/4 inch needle (Disposable Dental Needles, J Morita). The needle was inserted between the pterygomandibular raphe and the coronoid notch then aspiration was performed, and 1.8 mL of 2% lidocaine with epinephrine 1:80,000 solution (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam) was deposited.

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 topical anesthetic 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?

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com

## 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

Funder No. 501100020595

## Study information

### Scientific Title

Comparative efficacy of various topical anesthetics during inferior alveolar nerve block in pediatric patients: a randomized clinical trial

### Study objectives

The null hypothesis was that no statistically significant difference would be noted in efficacy of 5% EMLA cream, 8% lidocaine gel, and benzocaine 20% gel in reducing pain from needle stick in children during the inferior alveolar nerve block.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 25/04/2023, Ethical and Scientific Committee of Damascus University (Damascus University, Mazzeh Highway, Damascus, -, Syria; +963 992647528; dean.dent@damascusuniversity.edu.sy), ref: N3905

### Study design

Tripleblind randomized parallelgroup active-controlled trial with three arms

### Primary study design

Interventional

### Study type(s)

Treatment

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

Dental pain

### Interventions

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### Intervention Type

Drug

**Phase**

Not Applicable

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

5% EMLA cream, 8% lidocaine gel, benzocaine 20% gel, 2% lidocaine with epinephrine 1:80,000

**Primary outcome(s)**

1. Pulse rate assessment. Participants' pulse rate was recorded using a finger pulse oximeter (Alpha, Prolix GmbH) at two time points: (1) at baseline, before IANB administration. (2) Immediately after IANB administration.
2. Behavioral pain assessment scale. The face, legs, activity, cry, consolability (FLACC) behavioral pain assessment scale was recorded during IANB administration.
3. Pain rating scale. The Wong-Baker FACES pain rating scale was used to gauge the pain experienced immediately after IANB administration. Children were presented with a range of faces on the scale and asked to select the one that accurately represented their pain level during the procedure.

**Key secondary outcome(s)**

There are no secondary outcome measures

**Completion date**

14/09/2023

## Eligibility

**Key inclusion criteria**

1. Children aged 6-10 years.
2. Healthy children.
3. Children with no previous dental experience.
4. Children requiring IANB for non-urgent dental treatment.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

10 years

**Sex**

All

**Total final enrolment**

45

**Key exclusion criteria**

1. Children are allergic to the anesthetic agents used.
2. Children with dental abscesses and/or fascial space infections.
3. Special health care needs children.

**Date of first enrolment**

06/06/2023

**Date of final enrolment**

14/09/2023

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

Syria

**Study participating centre****Damascus University**

Mazzeah Highway

Damascus

Syria

N/A

**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 Mawiamaherkarkoutly@hotmail.com

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		27/11/2024	21/01/2025	Yes	No