ISRCTN11021678 https://doi.org/10.1186/ISRCTN11021678

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

Submission date
06/11/2023

Recruitment status
No longer recruiting

Registration date
07/11/2023

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 ¾ 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
Dr Mawia Karkoutly

ORCID ID
http://orcid.org/0000-0003-0227-1560

Contact details
Mazzeh Highway
Damascus
Syria
-
+963 992647528
mawia95.karkoutly@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dental pain

Interventions
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 ¾ 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.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

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 measure
1. Pulse rate assessment. Participants' pulse rate was recorded using a finger pulse oximeter (Alpha, Prolinx 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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
04/04/2023

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

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
45

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
Mazzeh Highway
Damascus
Syria
N/A

Sponsor information

Organisation
Damascus University

Sponsor details
Mazzeh Highway
Damascus
Syria
-
+963 992647528
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
http://www.damascusuniversity.edu.sy

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 high-impact peer-reviewed journal.

Intention to publish date
31/01/2023

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?
Results article		27/11/2024	21/01/2025	Yes	No