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RESEARCH PROTOCOL

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جامعة محمد بن راشد للطب و العلوم الصحية
MOHAMMED BIN RASHID UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

RESEARCH PROTOCOL

STUDY TITLE:

Efficacy of Ethyl Chloride topical anesthesia application on the pain perception during intra-oral injections in children in comparison to 20% Benzocaine Gel– a single-blinded randomized controlled trial

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1. Introduction

Fear of the syringes and needle insertion is high among children. Reducing injection pain in children may help to provide overall comfort and well-being during the entire dental experience. Pediatric dentists are constantly searching for tools that may provide a more comfortable dental procedure. [1] A local anesthetic injection is one of the potent techniques to alleviate pain, but injection of local anesthetic itself is a major source of patient's fear. [2]

The challenge is to find an effective method that can be utilized in the pediatric population. Topical anesthetics function by blocking signal transmission in the terminal fibers of sensory nerves. Their effects are limited to the control of painful stimuli occurring in or just beneath the mucosa. [3]

Over the years, topical anesthetics have been used consistently in dentistry to prepare injection sites before needle penetration. Some studies have proved topical anesthetic capability in reducing pain perception during injections; however, others have concluded that topical anesthetics afford little more than placebo levels of effectiveness. [2,4] can be employed as a supplementary anesthetic technique to reduce intraoperative pain. [5]

Cryotherapy application is another endorsed strategy for reducing pain perception in patients that would be effective, efficient, and cost-effective. [2]

Cryoanesthesia is the application of ice on the anesthetic site to counter nerve conduction of pain from the site. Studies have reported that it lowers edema, nerve conduction velocities, cellular metabolism, and local blood flow. [2] The application of ice provides physiological and psychological benefits to the patients as it may distract them from focusing on their discomfort. Their use is much less widespread in dentistry; nevertheless, the use of ice sticks, refrigerants, or vapocoolants in the dental operatory to provide pre-injection anesthesia has been described in the literature.[2]

The methods used currently for topical anesthesia before dental injections mainly include different types of gel (e.g., lidocaine, prilocaine, or benzocaine 20% (BC)). Unfortunately, these gels tend to spread in the mouth due to lack of bio-adhesion, which may result in a reduced anesthetic effect [6] , unpleasant taste, and/or discomfort for the patient. [7] Furthermore, there is a risk of allergic reactions to several components in the different gels available for topical anesthesia[8] These factors are important reasons for developing and evaluating other substances and techniques for topical anesthesia. Ice was introduced during the nineteenth century as a safe method of local anesthesia, [9] and the use of cooling to reduce injection pain in the skin is well documented.[9,10]

Several explanations for the anesthetic effect of cooling have been proposed.[11] The topical cold application stimulates myelinated "A" fibers, thereby activating inhibitory pain pathways,[12] perhaps as part of the gate control system at the spinal cord level.[11] Furthermore, cooling causes cold-induced neuropraxia by decreasing the activation threshold of tissue nociceptors and the conduction velocity of nerve signals conveying pain.[6,13] Published studies evaluating ice as topical anesthesia in dentistry have been reported,[14] in addition to the intra-oral use of "refrigerant solutions" and "Vapocoolants" (such as 1,1,1,3,3-pentafluoropropane/1,1,1,2-tetrafluoroethane)[14,15] in palatal injections in adults. Although the effect of the refrigerant agent was found to be superior to BC20%, the use of ice and refigerants as topical anesthesics of the oral mucosa is not widely used in dentistry,[14] and appears to be non-existent in children.

Ethyl Chloride (EC) is a topical anesthetic agent used prior to rapid invasive techniques in minor surgery and sports medicine. [16] Historically, EC had been used as a general anesthesia agent for dental extractions.[17] However this practice ceased, with a focus on using it as a topical skin anesthesia agent and its uses as a sensibility testing agent[18,19] for teeth. When applied by aerosol on the skin, its rapid vaporization causes a tissue cooling of up to -20°C, generating an insensitivity of the peripheral nerves and, consequently, immediate local anesthesia lasting for

a few minutes. It does not present incompatibilities, interactions, or side effects beyond a local and transient hypersensitivity due to the cold.[1616] It had been suggested that because EC has a rapid effect, it can safely provide *cutaneous* analgesia in children in circumstances when it is impractical to wait for other local anesthetic preparations to take effect.[20] This could be extrapolated to the oral cavity and dentistry. However, as far as the authors know, although there is a registered trial ongoing at the moment [21] comparing EC effect on the oral mucosa in comparison to Lidocaine 5%, none have compared EC to BC 20% intraorally in children. Therefore this study aims to describe a new method of topical anesthesia of oral mucosa pre-local anesthesia injection and to compare the perceived pain, and subjective experience of two topical anesthetic agents, BC 20% gel and indirect application (using cotton palettes) of Ethyl Chloride spray.

3. Aims of the study

To compare the efficacy of 20% Benzocaine (BC) gel and indirect application of Ethyl Chloride (EC) spray, in reducing pain perception during local anesthesia infiltration in pediatric patients as well as describe a new simple method for topical anesthesia.

Specific objectives

- To compare the efficacy of BC and EC on buccal infiltration.
- To compare the physiological changes observed during the administration of local anesthesia with two pre-anesthesia topical application techniques (BC and EC).
- To compare the reported and observed pain perception of two topical anesthetic techniques (BC & EC) with different age groups and gender.

Research question

- How effective is the indirect application of EC topical spray anesthesia on pain perception during intraoral buccal injection in children in comparsion to BC 20%?

Null Hypothesis:

- There is no difference between EC topical anesthesia and BC 20% topical gel on the pain perception buccal during infiltration.

4. Materials and Methods

Study Design

The proposed study is a randomized control trial, single-blinded, following CONSORT Group [22], and Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines[23].

Population:

All healthy children and adolescents aged 7 to 10 seeking pediatric dental care who meet the inclusion criteria and sign the consent form (Appendix II).

PARTICIPANTS, INTERVENTIONS, AND OUTCOMES

A. Study Design / Location/ Candidates

The proposed study is a single-blinded randomized control trial. The study will investigate the pain perception during buccal infiltration using indirect EC spray (spraying EC 10 cm distance of the cotton palette and applied on the oral mucosa for 30 seconds at the site of injection prior

to local anesthesia injection) topical anesthesia and BC 20% topical gel applied for 30 seconds on dried oral mucosa and left for 1 minute using the end of an applicator stick (among seven to 10-year-old school children who attended Pediatric Dentistry Department at Dubai Dental Hospital (DDH), Mohammed Bin Rashid University (MBRU) in Dubai, the United Arab Emirates (UAE).

B. Eligibility criteria

Inclusion criteria

- Healthy children (ASA I) aged between 7 – 10 years old.
- Needing any maxillary buccal infiltration (anterior, middle, posterior)
- Had no prior history of local anesthesia.
- Frankl behavior III or IV
- Not taking any painkillers, or other drugs that would influence with their pain perception.

Exclusion Criteria

- History of a medically compromised condition and intellectual disability.
- Any allergy to local anesthesia.
- Active pathology at the site of injection.
- Prior history of intra-oral injection.
- Frankl behavior I or II.
- Children/parents not willing to participate in the study.
- Needle phobia.
- Patients require treatment under conscious sedation.

C. Sample Size

Cochrane sample size calculation for detecting a minimum difference of between visual analog score for the study and control groups

$$n = 2\left(\frac{z_{1-\alpha/2} + z_{1-\beta}}{SE}\right)^2$$

Where

$$SE = \frac{\mu_d}{\sigma_d}$$

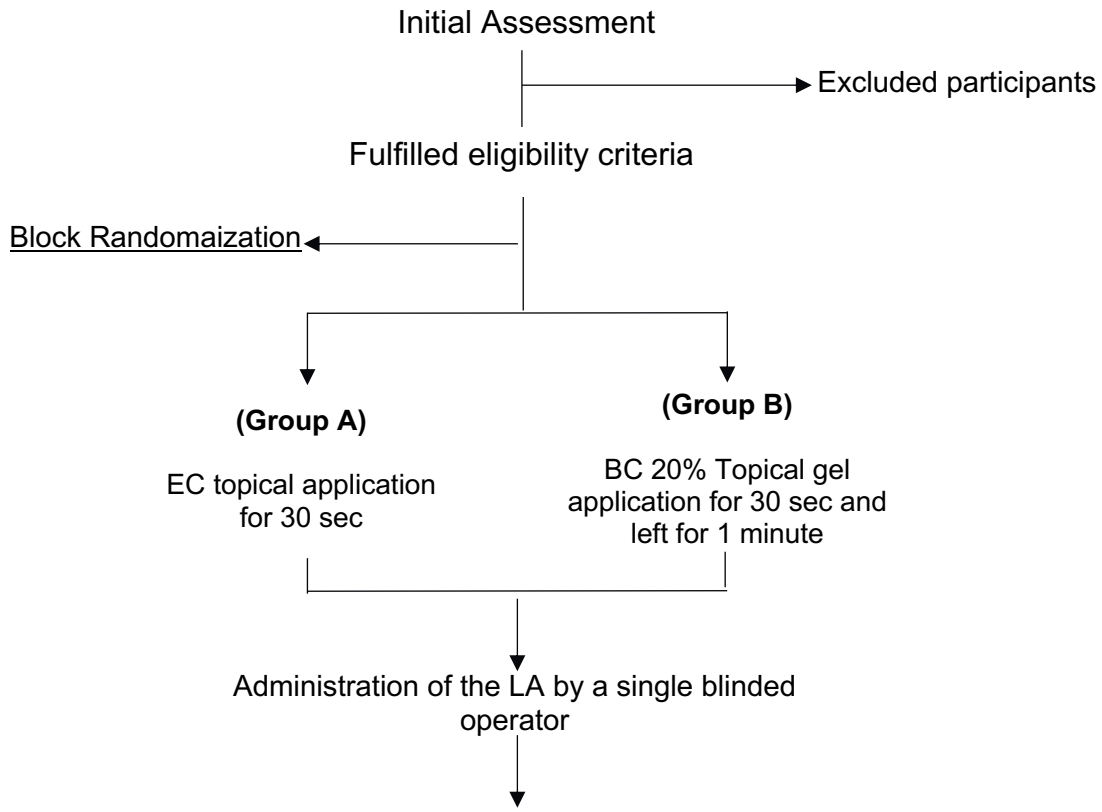
From the study of Lakshimi Lakshmanan and Vignesh Ravindran, the analog score yields the following measures for the study and control groups 40.66 ± 14.60 and 61.33 ± 9.73, respectively:

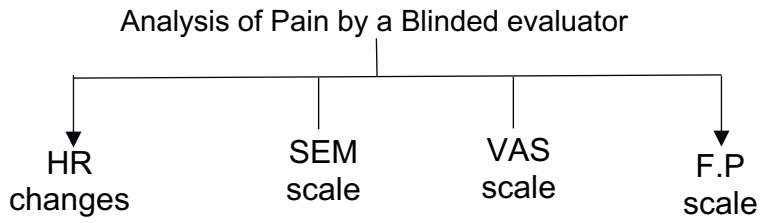
μd = 20.67 and δd = 12.41, the SE = 1.67, and the different scenarios according to power are as follows:

Power	α	$2(z_{1-\alpha/2} + z_{1-\beta})^2$	Sample size
0.95	0.01	31.5	53
	0.05	26	43
0.90	0.01	17.1	29
	0.05	21	35
0.80	0.01	20.1	34
	0.05	12.4	21

With a power of 80% and a significance level of 5%, the minimum sample is 21 children in each arm.

Fig 1: Study Flow Chart





BC (Benzoczine gel), EC (Ethyl Chloride), HR (Heart rate), SEM (Sound, Eye, Motor) index, VAS (Visual Analog Scale) and F.P (Face Pain scale).

D. Procedure and Indices:

Randomization, Blinding and the procedure with topical anesthesia (EC or BC):

Pre-local analgesia topical BC or EC technique will be selected randomly and applied per the protocol. A single calibrated operator (A.A) using randomly selected sealed envelopes that have been previously divided equally according to sample size arms. The selected envelope is then opened by the operator, who applies either the EC or BC topical anesthesia technique based on the chosen envelop. Followed by maxillary local analgesia buccal infiltration for a single tooth by a calibrated operator (A.A). The child is then observed and assessed by the blinded primary investigator (N.A) (to the topical anesthesia technique) for pain perception during local anesthesia infiltration based on the Sound, Eye, Motor index used in this study. The child is then asked to rate the Visual Analog Scale and Facial Pain Scale. Heart rate of the patient will be recorded as per below protocol.

1- Heart rate (HR)

Physiological changes in HR will be measured in beats per minute (bpm) and registered using a pulse oximeter. Each participant's heart rate will be recorded immediately before and after the injection using an FDA-approved pulse oximeter (SantaMedical SM-165 Fingertip Pulse Oximeter ®, China). The injection site will be dried and isolated using a cotton roll. A small

quantity of the topical anesthesia 20% Benzocaine (Dharma Research, Miami, USA®) anesthetic gel will be applied using the end of an applicator stick directly at the site of penetration for 30 s and then left for 1 min to ensure effectiveness. All the time periods will be calculated using the clock App timer available on an iPhone®. The injection of the anesthetic solution is performed according to the standard technique mentioned below. Directly after the injection, the pulse rate will be recorded a second time.

Protocol for injection of local anesthetic solution:

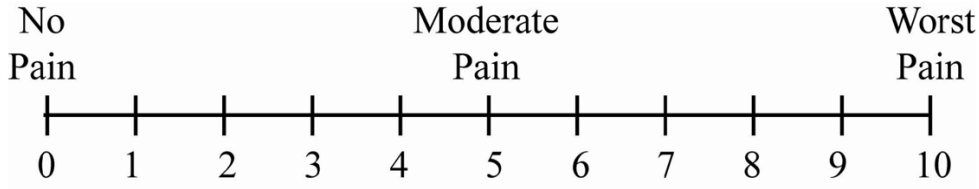
The injection will be made with 1.8 ml Lidocaine 2% (DENTSPLY Pharmaceutical, USA®); (adrenaline: 1:100.000), delivered in cartridges using a 27—gauge short needle (0.4×25 mm, C-K jet). A sterile non-aspirating syringe will be used, as recommended for infiltration anesthesia for maxillary teeth. The anesthetic solution will be administered into the buccal sulcus of the tooth following a standard technique. The syringe will be held parallel to the long axis of the tooth while the tissue is pulled out. Next, the needle will be inserted into the mucobuccal fold above the apex of the tooth at a 45° angle with the buccal cortical plate of the bone and with the gauge facing the bone. A few drops of the local anesthetic solution will be deposited immediately before the needle enters the tissue. After 2 to 3s, the needle will advance apically until the bone is contacted without penetrating the periosteum. The rest of the solution is then administered slowly over approximately 1 min. The needle is then withdrawn gently and slowly.

2- Sound, Eye, Motor (SEM) Index

Observations	1 comfort	2 mild discomfort	3 moderately painful	4 painful
Sounds	no sounds indicating pain	non-specific sounds; possible pain indications	specific verbal complaints "OW" raises voice	verbal complaint indicates intense pain, e.g. scream, sobbing.
Eyes	no eye signs of discomfort	eyes wide, show of concern, no tears	watery eyes, eyes flinching	crying, tears running down face
Motor	hands relaxed no apparent body tenseness	hands show some distress or tension; grasps chair due to discomfort, muscular tension	random movement of arms or body without aggressive intention of physical contact, grimace, twitch	movement of hands to make aggressive contact, e.g. punching, pulling head away

During the insertion of the needle, the operator will evaluate the patient's behavior for pain perception using sound, eye, motor (SEM) scale and visual analog scale (VAS).[2]

3- Visual Analog Scale (VAS)



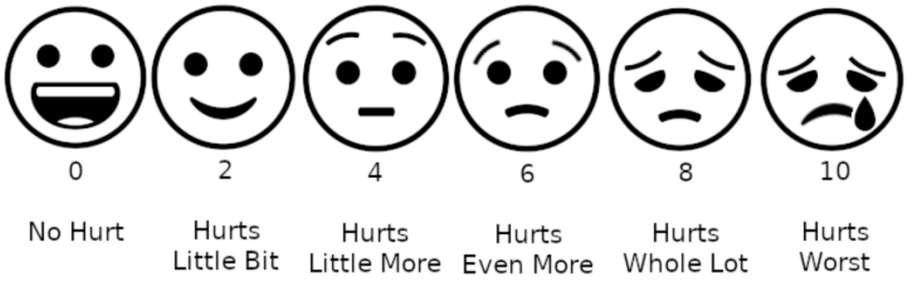
1-3 = mild pain
4-6 = moderate pain
7-10 = severe pain

The VAS scale is a 100-mm long horizontal line labeled "no pain: at one end and "worst pain possible" at the other. [2]

Participant's ratings:

After each procedure (EC or BC), the participants are asked to evaluate the degree of pain (primary outcome) they experienced using the Facial Pain Scale below.

4- Face Pain Scale



These faces show how much something can hurt. This face (point to leftmost face] shows no pain. The faces show more and more pain [point to each from left to the right] up to this one [point to rightmost face] - it shows very much pain. Point to the face that shows how much the child is hurt. Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so ''0' = 'no pain' and ''10' = 'very much pain. Do not use words like "happy' and ''sad'. This scale is intended to measure how children feel inside, not how their face looks. Brief word instructions: Point to each face using the words to describe the pain intensity. Ask the children to choose a face that best describes their pain and record the appropriate number. [2]

E. Piloting and Calibration

The study design and methodology will be piloted on five patients. In addition, Intra-and-Inter examiners calibration will be done on recording the indices and topical and local analgesia application techniques with a consultant in pediatric dentistry.

F. Data Collection

The data will be collected by the principal investigator (N.A), and the data collection sheet will record the findings obtained using a Microsoft Excel® standard proforma (Appendix I). Each participant will have a specifically coded data collection sheet. Initially, the data collection sheet will be identifiable by the child's name. Once the data collection sheet and the consent (Appendix II) are checked for completeness, the data collection sheets will be coded, and the patient's identifications will be covered for the patient's confidentiality.

G. Study Timeline

October 2022	Writing the Protocol
April 2023	IRB Approval, Study Registration, and Pilot Study
May – August 2023	Data Collection and randomization
September 2023	Data analysis and results
October 2023	Discussion and Conclusion

H. Statistical Analysis

Data will be entered into a computer using SPSS® for windows version 28.0 (SPSS Inc., Chicago, IL). Descriptive statistics will be used to describe categorical and continuous variables by proportion and measure of tendency, and measure of dispersion, respectively. The continuous measurements: score of analog and other variables (H) will be tested for normality using Shapiro Wilk. Comparisons between two arms will be administered on the function of the normality test using Parametric (T-test, chi-square) or non-parametric (Mann-Whitney test or exact fisher test). A P-value of less than 0.05 will be considered significant in all statistical analyses.

I. Ethical considerations

All patients fulfilling the basic inclusion criteria will be eligible for participation. The Principal Investigator will be responsible for identifying those prospective patients who do not fulfill the eligibility criteria so that they are not approached. Eligible patients will be approached in the clinic, invited to participate and subsequently examined by the clinical investigator to verify eligibility. The purpose of the study will be explained to parents/guardians and the consent

form will be provided to those who fulfill the study and assent/agree to participate. Children and parents/guardians will be given time to carefully read the consent form. It will ensure that they fully understand the consent form, and any questions will be answered. The participants will be expected to assent, i.e., affirmatively agree, to participate in the research project, and their parents/guardians will provide consent. The researcher obtaining informed consent will not be providing the treatment in order to avoid any appearance of undue coercion.

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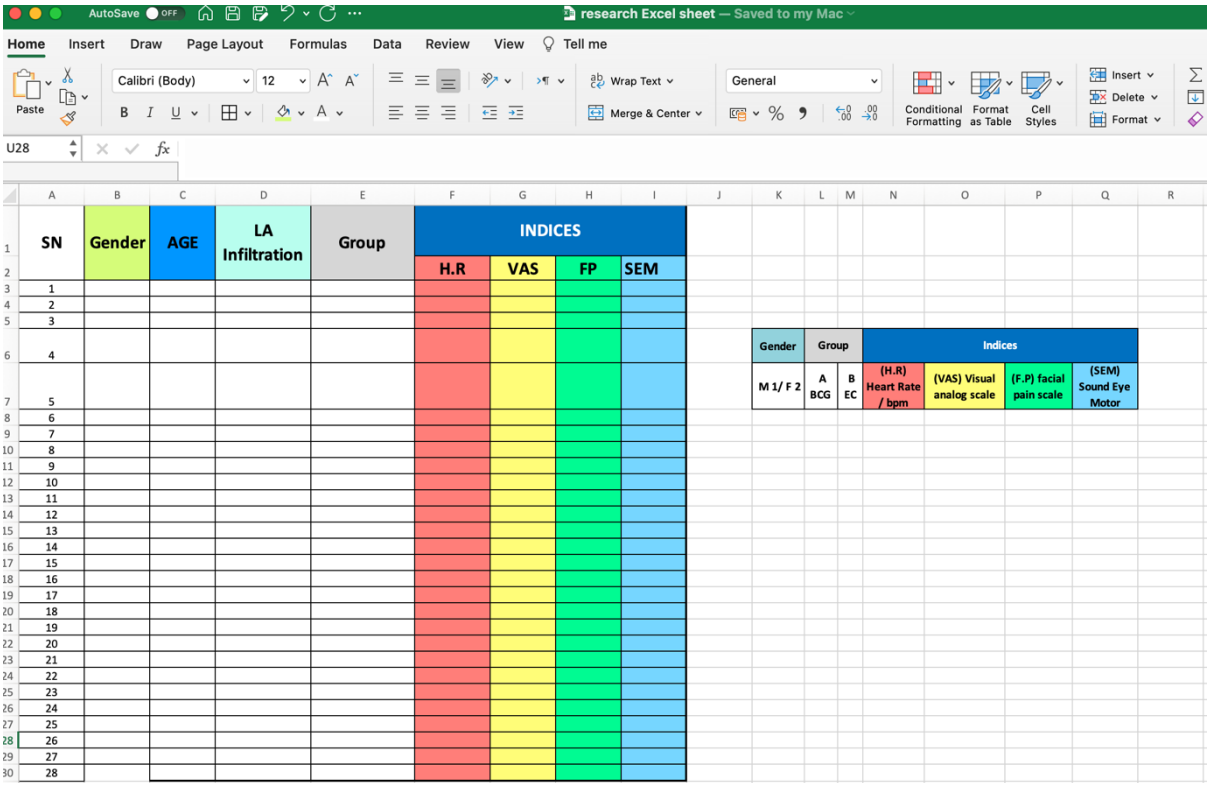
Appendix I



SN	Gender	AGE	LA Infiltration	Group	INDICES			
					H.R	VAS	FP	SEM
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Gender	Group		Indices			
M 1/ F 2	A BCG	B EC	(H.R) Heart Rate / bpm	(VAS) Visual analog scale	(F.P) facial pain scale	(SEM) Sound Eye Motor

Appendix I I

Consent Form

Title of the study: Efficacy of Ethyl chloride topical analgesia application on the pain perception during intra-oral injections incomparison to Benzocaine 20% – a single-blinded randomized controlled trial.

Principal Investigator: Dr. Nagah Abdelrahman, Department of Paediatric Dentistry, Hamdan Bin Mohammed College of Dental Medicine, Building 34, Dubai Healthcare City, Dubai, UAE. Telephone: (055) 122-5599.

Please take your time to review this information form, and feel free to consult with or discuss this study with your dentist, colleagues, family, friends, and/or physician before deciding whether or not to participate. If you have any questions regarding the study or any related issues we encourage you to ask the principal investigator, as listed above. This consent form may contain words that you do not understand. Please ask the research staff to explain any words or information you do not clearly understand.

Purpose of the study

This study is being conducted by the Hamdan Bin Mohammed College of Dental Medicine, Department of Pediatric Dentistry; to compare the efficacy of 20% Benzocaine (BC) gel and indirect application of Ethyl Chloride (EC) on cotton palette, applied on the oral mucosa prior to needle stick and injection of local anaesthesia at reducing pain perception during LA infiltration in pediatric patients as well as describe a new simple method for topical anesthesia.

Study procedures

If you choose to take part in this study, the following procedures will happen: The Benzocaine gel (20%) or indirect Ethyl Chloride spray will be applied on the mucosa prior the injection used in order to start the treatment.

You may stop participating in this study at any time. However, if you decide to stop participating, we encourage you to talk to the research staff first.

Risks and discomforts

There are no recognized risks or discomforts that may be caused to your child by participation in the study.

Benefits

There may or may not be a direct benefit to your child from participating in this study. We hope the information we collect will help us and parents to better recognize the best type of topical anesthesia for the children.

Cost/Payment

There is no cost to you for participating in the study and you will receive no payment or reimbursement for any expenses related to taking part in this study.

Alternatives, you should feel no obligation to participate in the study.

Confidentiality

All information obtained from this study is confidential and will remain so. Information gathered in this study may be published or presented in public forums; however, your name and other identifying information will not be used or revealed. In any published data, your identity (and your child's) will be protected and treated as confidential according to the Personal Health Information Act of UAE. To protect your identity, every participant will be given a Study Number instead of their name in all documents related to the study. All information obtained from this study will be used strictly for research purposes only. If the study information is used in any subsequent investigation, your consent will be taken.

Hamdan Bin Mohammed College of Dental Medicine Research Ethics Committee may review study records for purposes of quality assurance only. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

All records relating to this study will be kept in a secure, locked area and only those persons identified will have access to these records. If any of your child's medical/research records need to be copied to any of the above, his/her name and all identifying information will be removed. No information revealing any personal information such as your/your child name, address or telephone number will leave the HBMCDM.

Voluntary participation / Withdrawal from the study

Your decision to allow your child to participate in the study is voluntary. You may refuse to give consent for child to participate in the study or withdraw from it at any point in time. If the research staff feels that it is in your child best interest to withdraw her/him from the study, they will remove you without your consent.

We will tell you about any new information that may affect your child health, welfare, or willingness to stay in this study.

Questions

Please feel free to ask questions regarding the study or anything related to it that requires further clarification.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this study with Dr. Nagah Abdelrahman and/or his research staff. I have had my questions answered in a language I understand. All risks, benefits, costs, and alternatives regarding this study have been thoroughly explained to me. I believe that I have not been unduly influenced by any research team member to participate in the study by any statements or implied statements. Any relationship I or my child may have with the research team has not affected my decision to participate. I understand I will be given a copy of this consent form after signing it. I understand my and my child's participation in the study is voluntary and I may choose to withdraw my child from it at any point in time. I freely agree to participate in this research study and I give consent for my child to participate in the research study as well.

I understand that any information regarding my child's identity will be kept confidential, but that confidentiality cannot be guaranteed. I authorize the inspection of any of my records related to this study by the Hamdan Bin Mohammed College of Dental Medicine Research Ethics Board for quality assurance purposes.

By signing this consent form I have not waived any of the legal rights that I or my child have as a participant in a research study.

Parent/legal guardian's signature: _____
Date: _____ (day/month/year)
Parent/legal guardian's printed name: _____

I, the undersigned, attest that the information in the participant Information and Consent Form was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative and that the consent to participate in this study was freely given by the participant or the participant's legally acceptable representative.

Witness signature: _____
Date: _____ (day/month/year)
Witness printed name: _____