Faculty of Dentistry
Department of Pediatric Dentistry and Dental Public Health

Study Protocol and Statistical Analysis Plan

Masters Degree In Pediatric Dentistry
Academic Year 2020-2021
Dr. Rodaina Helmy

Title: EFFECTIVENESS OF COMPUTER - CONTROLLED INTRALIGAMENTARY LOCAL ANAESTHESIA IN EXTRACTION OF MANDIBULAR PRIMARY MOLARS: RANDOMISED CONTROLLED CLINICAL TRIAL

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Keywords: Computer – controlled, Intraligamentary, Local anesthesia, Nerve block, Articaine, Pain, Extraction.

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OUTLINE

ABSTRACT

Background: Exodontia poses a psychological threat for children, increasing the need for profound local anesthesia to assure painless extraction and maintain child cooperation on the dental chair. Computer-controlled Intraligamentary anesthesia (CC-ILA) affects only the tooth to be treated with minimal pressure, eliminating the side effects of other conventional techniques.

Purpose of the study: To evaluate the effectiveness of CC-ILA injection in eliminating pain during extraction of mandibular primary molars compared to inferior alveolar nerve block (IANB) technique.

Method: The study will be a double-blind randomized controlled clinical trial, parallel design. A total of 50 healthy children aged 5-7 years, will be selected from Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University, Egypt. Children will be selected with scores 3 or 4 Frankl behavioral rating scale. Each child selected will have at least one mandibular primary molar that is indicated for extraction. Written informed consent will be obtained from guardian. Participants will be randomly allocated into two groups according to the technique of anesthesia that will be used. Group I (test group) will receive CC-ILA, while group II (control group) will receive IANB. Heart rate will be used as vital parameter of pain, and will be recorded at base line, during injection and during extraction procedure. Pain reaction will be assessed objectively by two investigators using Sensory, Eye, Motor (SEM) scale, while subjectively the pain will be evaluated by asking the child to express his experience using a modified face scale from the Maunuksela scale.

Results: Data will be collected, tabulated and statistically analysed to obtain the results and conclusions of this study.

Keywords: Computer – controlled, Intraligamentary, Local anesthesia, Nerve block, Articaine, Pain, Extraction.

INTRODUCTION

Child management is a primary challenge facing pediatric dentists routinely. Uncooperative behaviour can significantly affect treatment quality, time, and increase the possibility of child injury during treatment as mentioned by Ingersoll and Ingersoll.[1] Acknowledgement of various behaviour management techniques, operating skills, and most importantly providing profound local anaesthesia are critical to deliver high quality dental service.[2]

Local anaesthetic (LA) forms the backbone of pain control techniques in dentistry. Although it is considered one of the painful procedures in daily dental practice, especially for children, however, its obligatory to use LA to eliminate pain during the various dental procedures and maintain child cooperation during the dental session.

Pain is defined by The International Association for the Study of Pain Subcommittee on Taxonomy in 1979 as "the unpleasant sensory and emotional experience arising from actual or potential tissue damage."[3, 4] Profound LA facilitates successful restorative and surgical treatment. Exodontia is one of the procedures that demand profound local dental anaesthesia to control high levels of pain and stress and reduce adverse reactions.[5]

A rapidly acting, potent LA drug is the gold standard. In the late 1940s, a new group of local anesthetic compounds, the amides, was introduced. The initial amide local anesthetic, Lidocaine, was used for pain control in dentistry worldwide.[6] Later in the mid-1970s, Articaine, a more potent Amide-type LA drug was first introduced in Germany by Rusching et al,[7] then in 2000 by the US Food and Drug Administration (FDA), and later in 2004, it has been approved by the Therapeutics Goods Administration for clinical use in Australia.[8]

Articaine is 1.5 times more potent than lidocaine;[9] its unique chemical composition enhances its lipid solubility, which increases its uptake by neurones providing an early onset.[10] Malamed (2000)[11] stated that Articaine 4% with epinephrine 1:100,000 provides total pain relief during most dental procedures, as it can effectively penetrate soft and hard tissues and is highly diffusible compared to other local anesthetics.[8] However, it is only available in high concentrations. Therefore, it is not recommended for children less than 4 years.[9, 12]

A study conducted by Vika and Skaret (2008)[13] reported that LA injections seemed to cause more anxiety than the treatment process itself, and may even lead to completely avoiding treatment. Therefore, pediatric dentists are always searching for the least painful LA technique to reduce pain, anxiety and maintain child cooperation.

Historically, the Inferior Alveolar Nerve Block (IANB) is the technique of choice for anaesthetising mandibular primary and permanent molars.[14, 15] It provides anesthesia to all tissue innervated by the including teeth, bone, lip, gingiva, and mucous membrane up to the midline of the related part. Due to the proximity of the Lingual nerve, it is also anaesthetized by the same injection, so the lingual side of the gingiva, the floor of the mouth and anterior two thirds of the tongue become numb.

As the IANB anesthetizes a wide area other than the teeth, patients encounter loss of sensitivity, as well as total or partial loss of function of the facial muscles and tongue for the duration of the anaesthesia which may last up to two hours.[10] Temporary hindering of patients' daily life with limited speech ability, eating, and most importantly, the risk of cheeks and lip biting are major drawback of this technique. Moreover, a rare but major complication of IANB anaesthesia is the injury of the mandibular nerve that could result in permanent impairment of the nerve function.[11,12]

In an attempt to overcome the limitations of the IANB technique, other methods have been advocated such as Intraligamentary Anaesthesia (ILA). This technique was introduced by Chompret (1920).[16] Intraligamentary Anaesthesia is a method of intra osseous injection with LA reaching the cancellous space in the bone via the periodontal ligament (PDL).

Intraligamentary Anaesthesia can be a very effective alternative technique in children, as it can help lessen the struggle of achieving successful anaesthesia during single tooth treatment.[17, 18] It can have superior features in cases where anatomical variations are present and eliminating soft tissue injury which is a major concern while using other techniques. Moreover, it aids in treatment if teeth in different quadrants that are being summoned in a single visit, which helps both pediatric dentist and the child to avoid management complications associated with multiple dental visits. Many studies have proven that ILA does not cause any secondary complications if carefully applied. It causes very little pain if at all, rapid onset and allowing to start the dental work immediately.[19]

Nevertheless, it is believed that ILA has higher levels of post-operative pain than conventional techniques, and its duration only lasts for around 20 minutes.[20-22] Two studies reported periodontal abscesses and deep pocket formation after ILA.[23, 24] Hence, it should not be used for children suffering from cardiovascular problems as they are at more risk of developing subacute bacterial endocarditis.[25, 26]

Intraligamentary Anaesthesia is delivered manually via conventional, or high-pressure syringes,[27] or using computer-controlled local anaesthetic delivery systems (CCLADS).[28] There are some potential problems with the conventional intraligamentary technique. One such problem is the high pressure required to inject the anesthetic solution, which may lead to breakage of the glass cartridge with a conventional syringe.[29]

The Wand-STA Single Tooth Anaethesia is a CCLADS launched in 2006 by the manufacturers of the Wand Compudent system.[30] It's the only delivery system with incorporated dynamic pressure sensing (DPS) technology to monitor real-time pressure.[31] It is capable of identifying the periodontal ligament tissue and enables the clinician to maintain the correct needle position within the periodontal ligament when performing ILA. Developed by Dr. Mark Hochman, the STA-Intraligamentary Injection represents a new concept in local dental anesthesia techniques.[32]

The system is activated by a foot control that allows a more precise and accurate LA delivery at a decreased steady pressure and volume via the intraligamentary route, regardless of the tissue resistance. This helps reduce tissue distortion and thus potentially minimizing the painful experience of ILA. However, it is significantly more expensive than a PDL-syringe and handling of the STA system may be complex for less trained dentists.[33]

Garret-Bernardin and Cantile (2017)[34] showed that computerized injections are better tolerated and reduced pain perception in 7 – 15 year old patients compared to the traditional syringe during routine dental treatment.[35] In another study conducted on primary teeth, Tekin and Ersin (2012)[36]reported that a significantly higher mean Sound, Eye and Motor (SEM) score of pain reaction for IANB group was recorded in comparison to conventional ILA during both injection and extraction periods of mandibular primary teeth ($p < 0.005$).

Various studies report adequate anesthesia with computer controlled intraligamentary injection for primary tooth cavity preparation and pulpectomy as well as permanent tooth extraction.[29, 33, 37-39] However, limited studies have been conducted to evaluate the efficacy of computer-controlled-ILA (CC-ILA) for extraction of primary molars.[30]

This study will compare the pain experience of the experimental group (CC-ILA) and control group (conventional injection by IANB) during injection and its effectiveness in eliminating pain during extraction of mandibular primary molars in pediatric patients. The null hypothesis is there will be no difference in the pain experience with the use of CC-ILA compared to the IANB in pediatric patients.

AIM OF THE STUDY

Primary aim:

- To evaluate the effectiveness of computer – controlled Intraligamentary Anaesthesia in eliminating pain during extraction of primary mandibular molars compared to Inferior Alveolar Nerve Block.

Secondary aims:

- To assess and compare the pain experience during Local Anaesthesia injection of mandibular primary molars between computer – controlled Intraligamentary Anaesthesia and conventional Inferior Alveolar Nerve Block.
- To assess and compare the pain experience during extraction of mandibular primary molars when using the two different anaesthesia techniques.
- To record the occurrence of any adverse events.

RESEARCH DESIGN

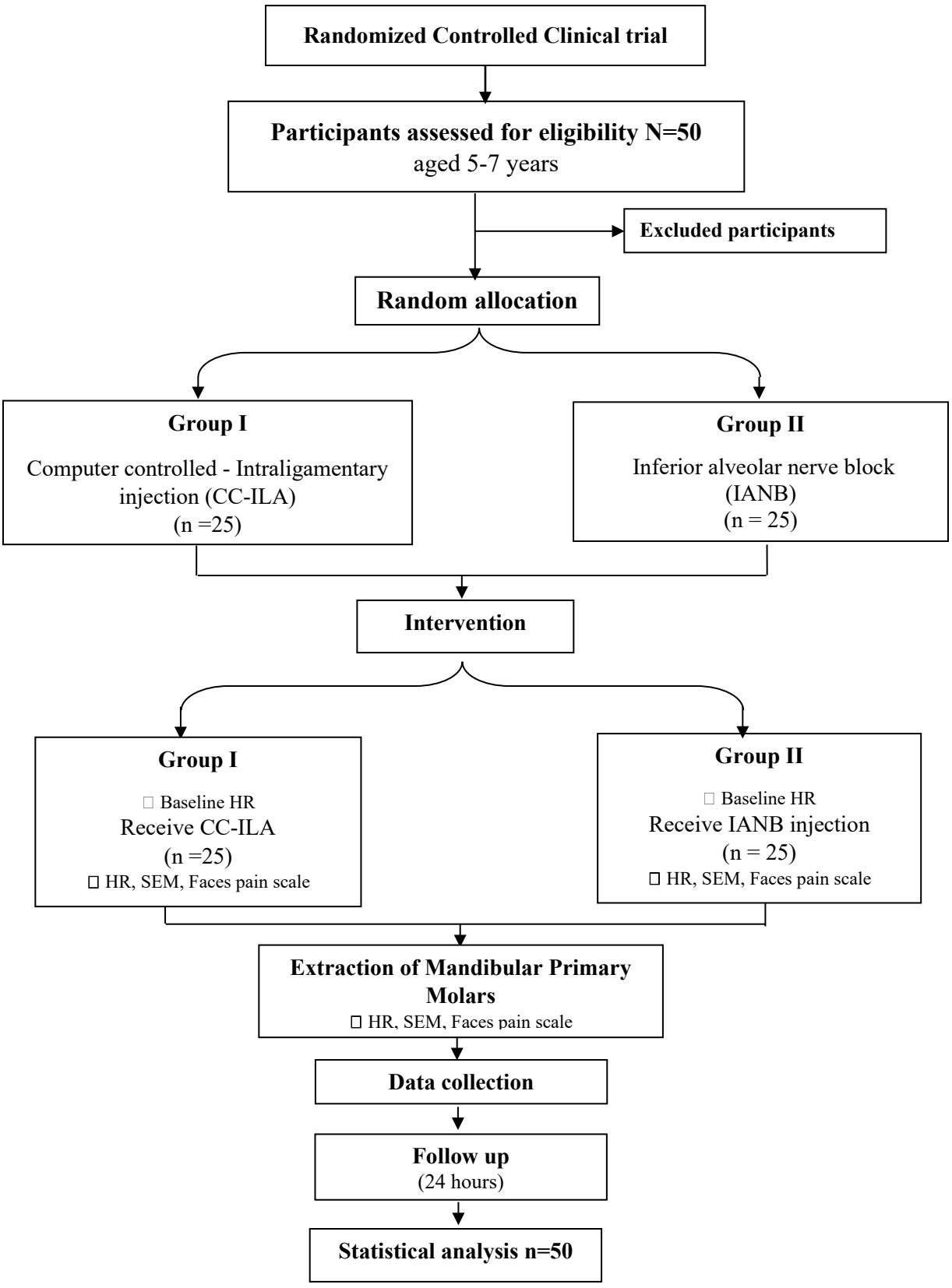

Figure (1): Flow Chart Study Design

PLAN OF THE STUDY

Study design

The study will be a two-arm randomized controlled clinical trial. It will be setup and reported according to the CONSORT guidelines.[40] The PICOT question will be: do pediatric patients aged from 5-7 years (Population; P) assigned to receive CC-ILA (Intervention; I) in comparison to inferior alveolar nerve block conventional injection (Control; C) show less pain during injection and extraction of mandibular primary molars (outcome; O) in twenty-four hours (time; T)?

Study setting and location

Participants will be recruited from Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University, Egypt.

Sample size estimation

The sample size was calculated based on results obtained from previous studies of similar nature. Sample size was estimated assuming alpha error= 5% and study power= 80%. Tekin et al [36] reported mean ± SD Sound, Eye and Motor (SEM) score = 3.93 ± 1.223 when intraligamentary anesthesia (ILA) was used, and 5.17 ± 1.891 when inferior alveolar nerve block (IANB) was used. Based on comparison of means, sample size was calculated to be 25 per group, and the total sample size required to compare the effectiveness of CC-ILA technique versus IANB during extraction of primary mandibular molars = number of groups × number per group= 2 x 25 = 50.[41] The sample size was calculated using powerandsamplesize.com calculator.[42]

Criteria for sample selection:

a) Eligibility Criteria

- Age range from 5 – 7 years.
- Children free of any systemic disease or special health care need (ASA I).[43]
- No previous bad dental experience.[44]
- Positive or definitely positive behaviour during preoperative assessments according to the Frankl Rating Scale (score 3 or 4) (Appendix I).[45]

- Patients whom their mandibular primary molars are indicated for extraction:[46, 47]
    - Clinical signs and symptoms of pulp degeneration, such as swelling or sinus tracts.
    - Radiographic evidence of periapical or interradicular radiolucency.
    - Non restorable crowns.
    - Failed pulpotomies.
- Patients whose parents will give their consent to participate.

b) Exclusion Criteria for teeth [48]

- Root resorption affecting more than one third of the root length.
- Fractured roots due to trauma.
- Signs of mobility.
- Ankylosed roots.
- Active sites of pathosis in area of injection that could affect anaesthetic assessment.
- History of allergy to local anesthesia.

Materials

a) Topical Anaesthesia – Benzocaine gel 20%.*

b) 27-guage long anaesthetic needles.**

b) Local anaesthetic carpules: Articaine hydrochloride 4% with adrenaline 1:100,000.***

c) Equipment:

- Wand - STA Single Tooth Anaesthesia Device (Figure 2)****
- Disposable Wand – STA Handpieces with 30-guage 0.5-inch needles. ****
- Pulse oximeter.*****
- Dental anaesthetic syringe (non-disposable breech loading, metallic cartridge type).******
- Lower Full-crown Extraction forceps.*******

* Dharma Research, Inc. 5220 NW 72nd Ave Miami, FL 33166 USA.
** C-K Ject, CK Dental Ind. Co., LTD., Korea.
*** ARTINIBSA, Inibsa Dental S.L.U, 08185 Lliçà de Vall, Barcelona, Spain.
**** STA; Milestone Scientific, Inc., Livingston, NJ, USA
***** Zacurate,10101 Stafford Centre Dr. Ste B Stafford, Texas, USA.
****** BeehiveSolutionsLtd:10aHighview Parade. Woodford Avenue. Ilford. Essex. UK.
******* Likamed Plot # 117/2 A Model Town Ugoki, Sialkot, Pakistan.

Figure (2): Wand - STA Single Tooth Anaesthesia Device

Randomization

Participants complying with the inclusion criteria will be randomly assigned using a computer-generated list of random numbers.[49]

Allocation concealment

Each child included in the study will be given a serial number that will be used in the allocation. These numbers will be written in identical sheets of paper with the group to which each child is allocated and placed inside opaque envelopes carrying the respective names of the children.[50] A trial independent personnel will be assigned to the role of keeping the envelopes and unfolding them only at the time of the local anesthesia injection session so that the group the child is allocated to is concealed from the outcome evaluator.

Grouping

Participants will be randomly and equally allocated to one of the two arms (Figure 1).

- **Group I:** (experimental group n = 25) assigned to CC-ILA.
- **Group II:** (control group n = 25) assigned to conventional injection by IANB.

Blinding

The researcher (operator) who will perform all the injections and extractions as well as record heart rate measurements cannot be blinded to the type of intervention; a second impartial observer (evaluator) will record the Sensory, Eye, Motor (SEM) scale independently.[30] The statistician will be blinded to the treatment groups. Since the participants will also be blinded, therefore, the study will be triple-blind.

Examiner reliability

- For standardization, all clinical procedures will be performed by a single operator, who will be trained and calibrated for the Wand – STA system via training sessions by an expert through the manufacturing company, as it is too complex to be applied effectively without more appropriate training. Especially, the coordination between the foot pedal handling and the syringe has shown to be difficult.[33]
- Training on heart rate measurement using the pulse oximeter will be also planned.
- The second observer will be trained separately to assess pain using (SEM) scale by observing children undergoing dental procedures and classifying the child's behavior on videotapes. After a 7-day interval, the exercise will be repeated in order to develop an acceptable degree of examiner reliability. Intra-examiner reliability will be tested by Intraclass correlation (ICC).[51]

Clinical Procedure

Preliminary screening visit

- Full medical and dental history will be carried out to select patients. Those patients whose parents will give their consent to participate will be examined.[52] Proper diagnosis with thorough clinical examination, and intraoral periapical radiograph of the tooth to be extracted will be taken to ensure that the patient will match the inclusion criteria.

Patient Preparation [53]

- The child's dental visit will be a mean of introducing dentistry and acquainting the child to the dental unit and dental instruments using 'Tell Show Do' technique. No treatment will be done to the child in order to build a strong patient-dentist relationship.[54]

Intervention Visit

Psychological child preparation:

- The children will be told that their teeth will be put to sleep after placing some jelly and feeling a little pinch, in order to get rid of germs.
- Audible sounds will be heard while using STA in group I, so they must be informed.
- Subjects in Group II (IANB) will be told that their cheek will feel big and funny for some time.
- The procedure will be videotaped as a method of motivation to document their good behaviour.
- Patients will be positioned in supine position with the head and chest parallel to the floor and the feet slightly elevated.
- Mouth props may aid in maintaining a wide mouth opening.
- For both groups, soft tissues will be dried using (2 x 2 cm) gauze to enhance the absorption of the topical anaesthetic. Twenty percent Benzocaine topical anaesthetic gel will be used to obtund the discomfort associated with needle insertion. It will be applied at the site of needle penetration and left in contact with the soft tissues for one minute to optimise its effect.

Local Anaesthesia Administration

a) Wand-STA system:

- In the experimental group, CC-ILA will be administered using the Wand-STA system according to the manufacturer instructions, which is also concurrent with Mittal and Chopra (2019)[30]. It works with standardised 1.8 mL local anaesthetic carpules. The distalingual and mesiolingual line angles are the most effective for multi-rooted mandibular teeth.

- The injection is initiated by activating the STA mode when the foot control is tapped. A 30-gauge ultra-short disposable dental needle will be inserted in the PDL through the gingival sulcus at the distolingual line angle of the target tooth first, guided by constant audible tones and visual feedback. The needle should be directed approximately 30° angle to the long axis of the tooth and the bevel facing the alveolar bone. A total of 0.9 mL Articaine hydrochloride 4% with 1:100,000 epinephrine will be injected for each root as shown on a special indicator.

- During the anaesthetic solution delivery, the visual pressure indicator will be observed as the pressure is increasing from the red into the green zone. Tissue blanching may occur, which

suggests that enough LA has been delivered. Injection will be stopped by lightly tapping the foot pedal again. The dentist will wait 5 seconds before needle withdrawal. Same steps will be repeated at the mesiolingual line angle.[31]

b) Conventional technique:

- In the control group, a standard technique for the Inferior Alveolar Nerve Block (IANB) will be used supplemented with long buccal infiltration for the buccal gingiva. While the mouth is open as wide as possible, the index finger palpates the injection site.
- A 27-gauge disposable dental needle will be used to inject Articaine hydrochloride 4% with 1:100,000 epinephrine. The needle will be directed between the two primary molars on the opposite side of the arch, entering the tissues at the level of the occlusal plane or slightly lower until bony resistance is met.
- The needle is withdrawn 2mm to aspirate. Once negative aspiration is checked, the remainder of the solution is slowly deposited. The lip and/or cheek will be shaken as a method of distraction. Approximately 1.0 mL of LA will be delivered near the inferior alveolar nerve.[36] Two-thirds the needle length should be inserted.
- The needle is withdrawn, then 0.5 ml as a long buccal infiltration distal to the second primary molar is administered.[55]
- The operator will wait for 3-5 minutes before commencing dental treatment. Numbness will be tested with a dental probe on the gingiva immediately following the injection, and after each 10 seconds in case of CC-ILA and each 30 seconds in case of IANB till full numbness is declared and the time of onset of the anaesthetic effect will be noticed.
- In both groups, extraction will be accomplished according to AAPD guidelines.[56] Lower full crown forceps will be used to apply slow continuous palatal/lingual and buccal force allowing for the expansion of the alveolar bone to accommodate the divergent roots and reduce the risk of root fracture.
- Care will be taken to support the mandible with the non-extraction hand.
- If the patient suffered pain at any given time in the experimental group, the procedure will be abandoned immediately, IANB will be administered, and extraction will be carried out.

- Post extraction instructions will be given to the patient. They will be instructed to bite on gauze with firm pressure against the surgical site for 30 minutes. They should not disturb the surgical site or rinse vigorously on the day of extraction. According to the technique used, avoid scratching, or injuring the cheek, lips, or tongue if numbness is felt. They should avoid any physical exercise on the day of extraction. Cold soft food is recommended, as well as drinks to keep the child hydrated but without using a straw.
- Analgesics and/or antibiotics will be prescribed if required.
- Planning for space maintenance will be considered as well. All dental injections and extractions will be administered by the same operator, who will be assisted by a trained dental assistant.

Follow up

Following extraction, follow up after 24-hours will be planned via telephone calls to assess any adverse events.

Study Outcomes

I. Assessment of Child Pain Reaction

In the present study, pain will be assessed using the following 3 methods:

A. Physiologic method:

Heart rate (HR) is a physiological sign of pain.[57] It will be measured using a pulse oximeter. A brief demonstration using the pulse oximeter will be done, and the patient will be instructed to stay still and not to move his hands a lot in order to obtain accurate readings. The pulse oximeter will be placed on the patient's index finger to measure the baseline heart rate (before giving the LA), another measurement will be recorded during LA administration, and during extraction. Readings will be recorded at 2-minute intervals and the mean heart rate measurement will be calculated.

B. Objective method:

Sound, Eye, Motor (SEM) Scale (Figure 3), will be used as an objective method for pain assessment during LA administration and extraction. It comprises the following parameters: (1) Sound, (2) Eye, (3) Motor. For each child, the sounds, eye symptoms and body movements will be evaluated independently by a blind impartial observer using the recorded video tapes. The slightest manifestation of the sound, eyes, or motion of the patient is graded in four levels: comfort, mild, moderate, and severe discomfort, and subsequently given grades 1, 2, 3, 4, respectively. SEM score will be calculated by summing the three grades of the parameters. [58]

Parameter	Comfort	Mild discomfort	Moderate discomfort	Severe discomfort
Grade	1	2	3	4
Sound	No sound	Non-specific sound (probable pain)	Verbal complaint, louder sound	Verbal complaint shouting, crying
Eye	No sign	Dilated eye without tears (anxiety sign)	Tears, sudden eye movements	Crying, tears all over the face
Motor	Relaxed body and hand status	Muscular contraction, contraction of hands	Sudden body and hand movements	Hand movements for defence, turning the head to the opposite side

Figure (3): SEM scale for the assessment of children's behaviour

Subjective method:

A modified face scale[59] (Figure 4) from the Maunuksela et al[60] scale will be used to subjectively record pain during LA injection and extraction. It consists of three schematic faces with different facial expressions for happy and sad faces representing: (A) satisfaction; (B) indifference; and (C) dissatisfaction, respectively. Each child will be trained to use the scale by modelling and then asking each participant to think of the last time she/he felt something painful and to select the facial expression that best represented his/her experience of discomfort.

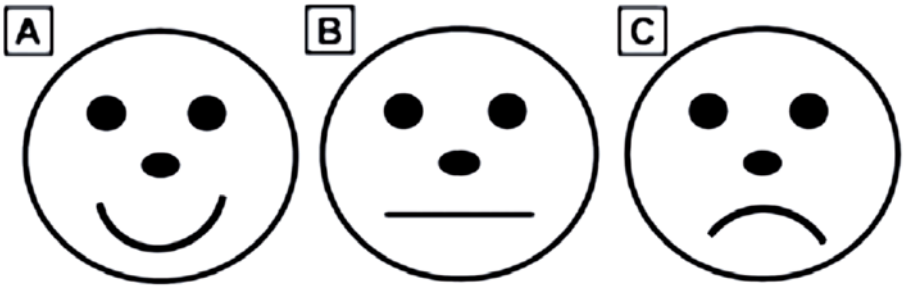

Figure (4): Faces scale modified from the Maunuksela et al scale.

(A) satisfaction; (B) indifference; and (C) dissatisfaction

II. Assessment of occurrence of adverse events

Parents will be recalled after 24 hours following extraction during follow-up phone calls. Recovery parameter questions will be asked to ascertain the occurrence of lip and cheek biting, post-operative pain, or any adverse events.

STATISTICAL ANALYSIS

All data will be collected; descriptive quantitative values will be summarised using mean and standard deviation, while count and percentage will be used for qualitative values. The data will be represented by suitable tables and graphs. Comparing between normally distributed data will occur using T- and Paired T-tests, while for not – normally distributed data, Wilcoxon signed-rank and Mann-Whitney U tests will be used.

All statistical analyses will be performed with statistical Package for Social Sciences* (SPSS) software version 21.[61] The significance level will be set at $P < 0.05$.

*SPSS Inc., Version 21.0, Chicago, IL, USA

ETHICAL CONSIDERATIONS

The study will be conducted following the ethical principles for medical research involving human subjects in Declaration of Helsinki.[62] Ethical approval will be obtained from the Research Ethics Committee, Faculty of Dentistry, Alexandria University before commencing the study.

The objectives, risks and benefits of the study will be explained to parents/ guardians and a signed informed consent will be obtained prior to treatment. (Appendix II). Verbal consent will be obtained from the children before the intervention.

Parents and children will be given age-appropriate oral hygiene instructions including proper teeth brushing twice a day especially before bedtime, as well as flossing if indicated. These measures will be demonstrated on a model. A fluoridated toothpaste and a brush will be provided to each participant on the day of the treatment.

All needed treatment will be provided to the child including any restorations, space maintainers and fluoride application. Post extraction instructions will be explained well to the parents and patients to ensure good wound healing. All the possible clinical and/or adverse outcomes will be explained to the parents and they will be asked to report immediately if any of them occurs.

PROBLEMS ANTICIPATED

1. Lack of compliance from patients and/or their parents.
2. Drop – out of patients during the follow up period.
3. Difficulty in collecting the proposed sample.
4. Difficulty in finding patients who fulfil the inclusion criteria of the study.
5. Negative behaviour of children due to the traumatic nature of the extraction procedure.

DURATION OF THE STUDY

Estimated time: 15 Months.

Tasks \ Months	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Proposal writing	✓	✓													
Sample selection			✓	✓											
Dental procedure					✓	✓	✓	✓							
Data management and statistical analysis									✓	✓	✓				
Writing thesis												✓	✓	✓	
Thesis submission															✓

ESTIMATED BUDGET

Estimated total budget 21,000 LE

No	Materials	Total price (LE)
1	Equipment	11000
2	Statistical analysis	2000
3	Computer services	2000
4	Printing services	2000
5	Publication cost	3000
6	Others	1000
Total		21000

ROLE OF SUPERVISORS

1. Assoc. Prof. Dr. Laila Moustafa El-Habashy

She will supervise the clinical work.

She will also help the student in interpreting results and revising the thesis.

2. Dr. Sarah Ibrahim Mohamed Zeitoun

She will supervise the clinical work.

She will also help the student in interpreting results and revising the thesis.

PUBLICATION POLICY

The study will be sent for either national or international journals for publication.

In order of:

1. Rodaina Hazem Mohamed Helmy

2. Laila Moustafa El-Habashy

3. Sarah Ibrahim Mohamed Zeitoun

APPENDICES

Appendix I

Frankl Behaviour Rating Scale

Rating	Behaviour	Mild discomfort
1	Definitely Negative	Refusing to play game, crying forcefully or fearfully, or any other overt evidence of extreme negativism
2	Negative	Reluctance to playing, uncooperative behaviour, and some evidence of negative attitude that is not pronounced
3	Positive	Acceptance of playing, willingness to comply with the dentist, cooperative behaviour
4	Definitely Positive	Good rapport with the dentist, interested in the environment, laughing, and enjoying the situation

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EFFECTIVENESS OF COMPUTER - CONTROLLED INTRALIGAMENTARY LOCAL ANAESTHESIA IN EXTRACTION OF MANDIBULAR PRIMARY MOLARS (RANDOMISED CONTROLLED CLINICAL TRIAL)

Name: Rodaina Hazem Mohamed Helmy

Summary Statement

Sample size was estimated assuming alpha error= 5% and study power= 80%. Tekin et al.[1] reported mean ± SD Sound, Eye and Motor (SEM) score = 3.93 ± 1.22 when intraligamentary anesthesia (ILA) was used, and 5.17 ± 1.89 when inferior alveolar nerve block (IANB) was used. Based on comparison of means, sample size was calculated to be 25 per group, and the total number required to compare the effectiveness of computer-controlled ILA technique versus IANB during extraction of primary mandibular molars = number of groups × number per group= 2 x 25 = 50.[2]

Software

http://powerandsamplesize.com/Calculators/Compare-2-Means/2-Sample-Equality.

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Maha El Tantawi; B.D.S, M.Sc, Ph.D

Professor of Dental Public Health
Alexandria University
Wednesday, January 20, 2021

Ethical Guidelines for Conduct of Research on Human Subject

- **Name of the Researcher:** Rodaina Hazem Mohamed Helmy
- **Name of the Department:** Pediatric Dentistry and Dental Public Health Department
- **Title of the Research:** Effectiveness Of Computer - Controlled Intraligamentary Local Anaesthesia In Extraction Of Mandibular Primary Molars: Randomised Controlled Clinical Trial

	ETHICAL CONSIDERATIONS	Yes	No
1	A clear scientific purpose is described	✓	
2	The research is for the good of the community	✓	
3	The study design is included	✓	
4	The estimated sample size document is attached	✓	
5	Informed consent of the human subject is signed by the Researcher	✓	
6	The research is based on previous animal studies or laboratory researches	✓	
7	The research will not lead to physical or mental suffering	✓	
8	There is no risk of disability, mortality or morbidity	✓	
9	Detailed invasive procedure (if present) with acceptable reasoning and related references are included	✓	
10	Safety of proposed intervention (if present) with related references are mentioned	✓	
11	Medical management for potential risk is involved	✓	
12	The risks are minimal in relation to benefit	✓	
13	Facilities for research are available	✓	
14	The investigator is scientifically qualified for this research & under supervision	✓	
15	Clinical termination when risk is expected is stated	✓	
16	The participants of research could quit the research if he/she suffers any complaints	✓	
17	Privacy & confidentiality of participants is assured	✓	
18	If any harm will occur he/she will be compensated	✓	

Recommendations of the Committee

• **Protocol is accepted from the ethics committee**	
• **Protocol is not accepted**	
• **Protocol should be revised for corrections**	

COMMENTS

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.....

Researcher Informed Consent for Ethics Committee

- **Name of the Researcher:** Rodaina Hazem Mohamed Helmy
- **Name of the Department:** Pediatric Dentistry and Dental Public Health Department
- **Title of the Research:** Effectiveness Of Computer - Controlled Intraligamentary Local Anaesthesia In Extraction Of Mandibular Primary Molars: Randomised Controlled Clinical Trial
- **Name of the Patient:** .....
- **ID number of the Patient:** .....

	ETHICAL CONSIDERATIONS	Yes	No
1	Statement to the participant that it is a research	✓	
2	Explanation is given to the participant of the research in clear understandable words about the procedure & its duration	✓	
3	The benefit of the research to the participant & others is described	✓	
4	The participant is informed about liable reasonable risk or discomfort	✓	
5	The participant is informed about any alteration in procedure if needed	✓	
6	Confidentiality is assured	✓	
7	The participant can quit at any time without any penalty	✓	

Signatures

• **Signature of the Participant:**	
• **Signature of the Researcher:**	Rodaina
• **Date:**	20/01/2021

Researcher Pledge

The researcher is responsible to fulfill this attached consent form that involving the ethical considerations for each Participant during the period of the study.

Signature of the Researcher

Rodaina

Researcher Application Form

1. **Name of the Researcher:** Rodaina Hazem Mohamed Helmy
2. **Title of the Researcher:** Instructor, Pediatric dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University.
3. **Address of the Researcher:**
   - E-mail: rodaina.Helmy@alexu.edu.eg.
   - Phone Number: 00201100001193
   - Fax Number .....
4. **Name of the Department:** Pediatric dentistry and Dental Public Health Department
5. **Degree of the Protocol:**

	MD		PhD		MS		Research work	
Domestic					✓			
Multicenter within Egypt								
International								

6. **Title of the Research:**

Effectiveness Of Computer - Controlled Intraligamentary Local Anaesthesia In Extraction Of Mandibular Primary Molars: Randomised Controlled Clinical Trial.

7. Type of the Research:

Clinical Trial	✓
Experimental Animal Study	
In vitro Biological Study (Studies of Biological Samples as; Cells, Fluids, Tissues, Extracted teeth etc. .....)	
In vitro Laboratory Study	
Cross Sectional Study (Survey, Case Control, Cohort etc. .....)	
Others ❖ *Please Mention The Research Type:*	

8. Subjects of Research:

Human	Adult Male	
	Adult Female	
	Child Male	✓
	Child Female	✓
Biological Samples as; Cells, Fluids, Tissues, Bone, Extracted teeth, Biopsy etc. ..... ❖ *Please Mention the Selected Subject:* ……..		
Animal Species		
Others ❖ *Please Mention The Research Subject:*		

9. Study Phase

Study Phase	Phase I [Laboratory]	Phase II [Cell, Fluid, Tissue]	Phase III [Experimental Animal]	Phase IV [Clinical Trial]
				✓

Study Design of Clinical Trials	
Randomization	✓
Placebo – Positive Control – Negative Control	Positive Control
Split Mouth	
Cross-Over	
Others ❖ *Please Mention The Study Design:*	

10. The Estimated Sample Size Document is attached:

Yes	✓	No	

11. The research provides potential benefits for the community:

Yes	✓	No	

12. Facilities for the research are available:

Yes	✓	No	

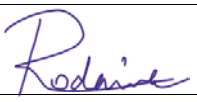
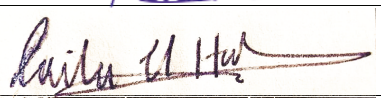
13. List the risks of the study:
Occurrence of complications or any adverse events.
Allergic reaction to local anaesthetic drug.
Panic attacks or lack of cooperation of the children during the treatment.

14. List the potential benefits of the study:
Decrease the pain during local anaesthetic injection and extraction of primary molars in children

15. The risks are reasonable to the potential direct benefits to the subjects, if any, or to the knowledge to be gained:

Yes	✓	No	

16. The researcher signed consent form is attached:

Names	***Signature***
The Researcher Rodaina Hazem Mohamed Helmy	
The Main Supervisor Associate Professor Laila Moustafa El-Habashy	
Date 21/01/2021	