ISRCTN14600773 https://doi.org/10.1186/ISRCTN14600773

Young patients' perceptions of intra bony local anesthetics and their usefulness in treating lower molars with pulp therapy and crowns

Submission date
02/08/2023

Recruitment status
No longer recruiting

Registration date
02/10/2023

Overall study status
Completed

Last Edited
22/11/2024

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
During dental procedures, pain management is essential, especially when working with young children. In dentistry, local anesthetic is the method of choice for minimizing the discomfort and pain related to dental treatment. Unfortunately, fear of local anesthetic causes many people to put off getting dental care, especially kids. Choosing the least painful local anesthetic method is therefore crucial. The ideal local anesthetic should be as painless and simple as possible, provide maximal performance, and need the fewest injections possible.
The study aims to test the usefulness of intra bony anesthesia and pain-related behavior, pain perception with children while performing pulp therapy and crowns

Who can participate?
Any healthy patient aged 5 - 9 years with two lower molars (one on each side) without any history of severe pain or swelling can participate in the study.

What does the study involve?
According to a randomization table, each patient will get pulp therapy on two primary lower molars and either standard syringe or intra boney anesthetic. The teeth will then be repaired with crowns.
Every 15 seconds for the duration of the injection time, two evaluators will assess the patient's behavior.
Following injections, a validated index will be used to assess the kids' sense of pain.
Using a scale for pain measurement, the effectiveness of local anesthetic will be evaluated by two impartial, blinded evaluators while the patient is being videotaped.

What are the possible benefits and risks of participating?
Participating in the study entitles the subject to free comprehensive dental treatment with no known risks.

Where is the study run from?
King Saud University, Riyadh (Saudi Arabia)

When is the study starting and how long is it expected to run for?
May 2022 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
E-22-6879

Study information

Scientific Title
Pain-related behavior, perception, and effectiveness of intraosseous local anesthesia (Quicksleeper 5®) in pulpotomies and stainless steel crowns of mandibular primary molars: a randomized controlled clinical trial

Study objectives
1. Difference in pain-related behavior and pain perception during local anesthesia injection between buccal infiltration and intraosseous (IO) anesthesia using Quicksleeper 5
2. Difference in the effectiveness of local anesthesia between intraosseous (IO) anesthesia using Quicksleeper 5 and buccal infiltration in treating pulpotomies and SSC of primary mandibular second molars
3. Difference in the complications of local anesthesia between intraosseous (IO) anesthesia using Quicksleeper 5 and buccal infiltration in treating pulpotomies and SSC of primary mandibular second molars

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/08/2022, King Saud University College of Medicine (PO Box 7805, Riyadh, 11472, Saudi Arabia; -; atuk@ksu.edu.sa), ref: E-22-6879

Study design
Interventional double-blind randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Intraosseous local anesthesia and its effectiveness in treating lower molars for pulp therapy and crowns

Interventions
Current interventions as of 22/11/2024:

part1
This study will include a total of 33 patients who fulfilled the inclusion criteria. Each patient will receive either intraosseous (IO) anesthesia using Quicksleeper 5 (experimental group) or traditional syringe (control group) according to a randomization table, and each patient will undergo a standardized pulpotomy procedure on two primary mandibular molars. The teeth will then be restored with stainless steel crowns (SSC).Before the start of the data collection phase, two pediatric dentists working in the Department of Pediatric Dentistry were calibrated to use the index for evaluating pain-related behavior. The procedures were video recorded, and two calibrated pediatric dentists evaluated the behavior of the patient using five pain-related behaviors during the injection. The videos were edited with a sound indicator to ensure that both evaluators checked the patient's behavior simultaneously. These behaviors were recorded as present or absent at every 15-second interval of the entire injection period (Versloot et al., 2008):
1. Bodily movement, defined as the movement of an extremity greater than 15 centimeters or the turning of the body, 2. Muscle tension, defined as visible tension in the hands (white knuckles) or tension throughout the body, 3. Crying or screaming, 4. Verbal protest, and 5. Bodily resistance, when necessary, to maintain control of the child. To calculate the mean score for pain-related behaviors, the occurrences of all five behaviors were added and divided by the number of intervals. Intraexaminer and interexaminer reliabilities were assessed using Cohen's kappa.
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The Wong–Baker Faces Pain Rating Scale (Hockenberry-Eaton, 2001) was used to evaluate the children's perception of pain following the injections. This index has been validated for the Saudi population (Baghlaf et al., 2015). This rating scale is appropriate for children aged three and above. Before administering anesthesia, the operator explained the faces in the scale to the patient with scripted instructions that were read to all patients, accompanied by pointing to each face and describing the associated pain intensity with the corresponding words. Immediately following the administration of local anesthesia, the child was asked, "Which looks like how you felt during the injection?" to select the face that best described their pain. The corresponding number was recorded

part 2
The effectiveness of local anesthesia was measured with each step of the pulpotomy procedure using the sounds, eyes, and motor (SEM) scale (Wright et al., 1991). This is a 12-point scale ranging from 3-12, and a lower score is better. The patients were video recorded. The videos were edited with writing, indicating each procedure to be evaluated; during placement of the rubber dam, drilling, opening of the pulp, removal of pulpal tissue (using a low-speed handpiece and restored with MTA), removal of the rubber dam, preparation for the SSC, and placement of the SSC. A calibrated independent blinded evaluator assessed the effectiveness in the mentioned procedures. The blinded evaluator scored for the seven steps during the procedure was taken, and then the mean score taken. The intraexaminer reliability assessed using Cohen's kappa.

Follow-up evaluation:

The parents of each patient were contacted by the operator within 2-4 hours of administering LA and asked if there are any postoperative complications and if numbness is still present. In addition, parents were asked about lip biting, swelling or pain at the injection site.

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Previous interventions:

This study will include a total of 53 patients who fulfilled the inclusion criteria. Each patient will receive either intraosseous (IO) anesthesia using Quicksleeper 5 (experimental group) or traditional syringe (control group) according to a randomization table, and each patient will undergo a standardized pulpotomy procedure on two primary mandibular second molars. The teeth will then be restored with stainless steel crowns (SSC). The procedure will be video recorded, and two trained dental assistants will evaluate the patient's behavior according to five distinct pain-related behaviors. The presence or absence of these behaviors will be recorded every 15 seconds for the duration of the injection period. Inter- and intra-evaluator reliabilities will be assessed using Cohen’s kappa. Following injections, the Wong–Baker Faces Pain Rating Scale will be used to assess the children's perception of pain. The effectiveness of local anesthesia will be measured with each step of the pulpotomy procedure using the sounds, eyes, and motor (SEM) scale. The patient will be video recorded, and two independent blinded evaluators will assess the effectiveness of LA during placement of the rubber dam, drilling, opening of the pulp (which will be announced by the operator), removal of pulpal tissue, removal of the rubber dam, preparation for SSC and the placement of SSC. Inter- and intraevaluator reliabilities will be assessed using Cohen’s kappa. The parents of each patient will be contacted after 2 hours of administering LA and will be asked if there are any postoperative complications.

Descriptive statistics will be performed first to report the demographic characteristics of the participating children. The average age and standard deviation as well as the frequency and proportion of sex distribution, adverse events, and drop-outs after which LA was used will be reported. For all outcomes, to study individual differences, the Wilcoxon test will be applied. Simple and multiple linear regressions will be performed to estimate the average difference in pain-related scores between buccal infiltration and IO anesthesia. The overall and age-specific average difference, with the corresponding 95% confidence intervals (95% CI), will be reported. To address the within-individual correlation of the outcome, for each age group in the full model, the standard error in our models will be adjusted to account for clustering and a stratified analysis will be performed. If assumptions of linear regression do not hold, we will perform generalized linear regressions addressing the violated assumption. The alpha level will be set at 0.05 to reject the null hypothesis, and all statistical analyses will be performed using Stata/MP Version 17.0 (StataCorp, College Station, TX).

Intervention Type
Mixed

Primary outcome measure
1. Pain-related behavior: 5 different behaviors (present or absent) measured every 15 seconds
2. Pain perception: Wong baker Scale. The patient will be asked once after giving the LA.

(added 22/11/2024)
3. The effectiveness of LA: (sound, Eye, Motor Scale). The blinded evaluators will evaluate the scores in 7 steps during the procedure, then the mean score will be taken

Secondary outcome measures
Current secondary outcome measures as of 22/11/2024:

1. Complications of intraosseous local anesthesia: patient's parents will be contacted after 2 - 4 hours after the procedure and will be asked standard questions

Eligibility

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Previous secondary outcome measures:

1. The effectiveness of LA: (sound, Eye, Motor Scale). The blinded evaluators will evaluate the scores in 7 steps during the procedure, then the mean score will be taken
2. Complications of intraosseous local anesthesia: patient's parents will be contacted after 2 - 4 hours after the procedure and will be asked standard questions

Overall study start date
20/05/2022

Completion date
13/06/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/11/2024:

1. Aged 4-9 years
2. Physically and mentally healthy
3. Positive or definitely positive behavior, assessed by taking the history of the patient; if the patient has no previous dental treatment, a treatment will be provided to the patient to assess the behavior
3. No contraindication for the use of local anesthesia
4. Not taking any analgesic before the appointment for at least 48 hours
5. No infection or inflammation on either side of the lower arch
6. Two lower second primary molars indicated for pulpotomy and SSC, i.e.:
6.1. No history of spontaneous or persistent pain
6.2. No pathological mobility
6.3. No tenderness to percussion
6.4. No swelling or sinus tract
6.5. No widening of the periodontal ligament space
6.6. Restorable tooth

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Previous inclusion criteria:

1. Aged 5-9 years
2. Physically and mentally healthy
3. Positive or definitely positive behavior, assessed by taking the history of the patient; if the patient has no previous dental treatment, a treatment will be provided to the patient to assess the behavior
3. No contraindication for the use of local anesthesia
4. Not taking any analgesic before the appointment for at least 48 hours
5. No infection or inflammation on either side of the lower arch
6. Two lower second primary molars indicated for pulpotomy and SSC, i.e.:
6.1. No history of spontaneous or persistent pain
6.2. No pathological mobility

6.3. No tenderness to percussion
6.4. No swelling or sinus tract
6.5. No widening of the periodontal ligament space
6.6. Restorable tooth

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
53

Total final enrolment
33

Key exclusion criteria
1. Physical or mental illness
2. Definitely negative or negative behavior
3. Presence of contraindication for using local anesthesia
4. Presence of infection or inflammation on either side of the lower arch
5. History of spontaneous or persistent pain
6. Pathological mobility
7. Tenderness to percussion
8. Swelling or sinus tract
9. Widening of the periodontal ligament space
10. Nonrestorable tooth

Date of first enrolment
01/02/2023

Date of final enrolment
13/06/2024

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Saud University
Dental University Hospital
Riyadh
Saudi Arabia
12372

Sponsor information

Organisation
King Saud University

Sponsor details
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Other

Funder Name
Investigator intiated and funded

Results and Publications

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

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The data will be stored in a non-publicly available repository of the clinical trial unit (CTU), King Saud University Medical City (KSUMC) (Galdrees@ksu.edu.sa). Patient videos will not be shared with anyone, and for other data the researchers will follow the protocol of KSUMC and the CTU.

IPD sharing plan summary
Stored in non-publicly available repository