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The use of computerized anesthesia 'QuickSleeper 5' in children undergoing dental treatment

Submission date 10/01/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/01/2022	**Overall study status** Completed	
Last Edited 11/06/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Dental local anesthesia is one of the most challenging concepts in pediatric dentistry for many reasons
1. Anatomical considerations of children make it somewhat difficult to achieve a high success rate with block anesthesia,
2. Pain caused by the injection itself can be one of the most common causes of cooperation lost in children and
3. Local complications caused by the local anesthesia are unpleasant for both child and parents, especially lip biting.
For these reasons, computerized intraosseous anesthetic devices like QuickSleeper 5 started to become more widespread recently in order to counteract all of the shortcomings associated with block anesthesia. However, clinical studies that touch on computerized intraosseous anesthesia devices are almost poor.
This was the reason behind conducting this study. The present study will compare between QuickSleeper 5 anesthesia and inferior alveolar nerve block (IANB) in children. The aim of this study is to evaluate the effectiveness, pain caused and complications associated with QuickSleeper 5 and compare it with block anesthesia as there is uncertainty about which is better or if they may be equivalent.

Who can participate?
cooperative children aged between 6-9 years who need bilateral pulpotomy treatment of mandibular second primary molars.

What does the study involve?
Children who participate in this trial will be exposed to both types of anesthesia (QuickSleeper 5 and IANB). The primary outcome of the study will be the effectiveness of anesthesia, pain caused by the injection, and local complications caused. The secondary outcome will be parental satisfaction.

What are the possible benefits and risks of participating?
Benefits: children who will participate in this trial will be anesthetized by two types of anesthesia with the least possible pain. in addition, their lower second primary molars will be treated.
Risks: as all contraindicated children to both lidocaine and epinephrine will be excluded, there will be no risk of participating in this trial.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run from?
August 2021 to August 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3079

Study information

Scientific Title
Evaluation of the effectiveness, pain, and complications of computerized intraosseous anesthesia in comparison to block anesthesia in children

Study objectives
1. QuickSleeper 5 is more effective than block anesthesia in anesthetizing mandibular second primary molars.
2. QuickSleeper 5 causes less pain than block anesthesia while anesthetizing mandibular second primary molars.
3. QuickSleeper 5 causes fewer complications than block anesthesia after anesthetizing mandibular second primary molars.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/09/2021, Ethics scientific committee at Damascus University (Mazzeh Street, Damascus, Syria; +963 9933490577; drsalloum74@hotmail.com), ref: 3079

Study design
Interventional double-blinded split mouth randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Anesthetizing primary molars in children

Interventions
This study will compare two types of dental anesthesia in children; the intervention type will QuickSleeper 5 (QS) and the control one will be an active control with an inferior alveolar nerve block (IANB).
The study will include 52 participants aged between 7-9 years and all of them need bilateral pulpotomy for primary mandibular second molars in order to perform the study in a split mouth design. All participants will be allocated equally into two groups; Group 1: starts the first session with QS and the second session with IANB and Group 2: starts the first session with IANB and the second session with QS.
A random allocation list will be carried out by using the website: www.randomalist.com, all of the participants will be numbered from 1 - 52 in order to allocate them randomly into the two study groups. After that, each child will pull a closed envelope to determine with which side they will start (right or left).
Half of the ampule (0.9 ml) of Lidocaine 2% with epinephrine 1:100,000 will be administered for each child in both types of anesthesia used (IANB and QS)
in the QuickSleeper injection, the insertion point will be between the first and second primary molars under the periodontal papilla.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
QuickSleeper 5 (Dental hi tech, France)

Primary outcome measure
1. The effectiveness of both techniques of anesthesia will be studied during the pulp treatment procedure
2. Pain caused by the anesthesia will be studied using both subjective method (Simplified Faces Pain Scale S-FPS) immediately after the injection and objective method (Face – Legs – Activity – Cry – Consolability scale FLACC) during the injection
3. Local complications of anesthesia will be studied at baseline, 24h, 48h and 1 week

Secondary outcome measures
Parental satisfaction will be studied after 1 week measured using a bespoke questionnaire

Overall study start date
13/08/2021

Completion date
13/08/2022

Eligibility

Key inclusion criteria
1. Healthy children who don't suffer from any systemic disease
2. Children aged between 6 - 9 years
3. Children who need bilateral pulpotomy for mandibular second primary molars
4. Cooperative children who are classified as definitely positive according to Frankel

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
52 children with two injections for each child

Total final enrolment
52

Key exclusion criteria
1. The existence of any chronic or acute infection in the area of injection
2. Children who have taken any analgesics in the last two days before the anesthesia
3. Children who have allergy to amide type of anesthetic solutions.
4. Children who are contraindicated to lidocaine injection (who suffer from liver cirrhosis, hepatitis)
5. Children who are contraindicated to vasoconstrictors injection (who suffer from hypertension, myocardial infarction, angina pectoris)
6. Children who do not show cooperation during the procedure

Date of first enrolment
02/03/2022

Date of final enrolment
07/07/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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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
01/08/2023

Individual participant data (IPD) sharing plan
The original data, along with the codebook and analysis scripts, will be stored in a non-publicly available repository.
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (muaaz.alkhouli@outlook.com)

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/06/2024	11/06/2025	Yes	No