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The use of computerized anesthesia in children suffering from an enamel defect that presents as discoloration of the first molars

Submission date	**Recruitment status**	[X] Prospectively registered
26/06/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/07/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/07/2022	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental local anesthesia for children's molars that have a discoloring enamel defect called molar incisor hypomineralization (MIH) is one of the most challenging concepts in dentistry. These teeth are difficult to anesthetize due to the presence of an increased amount of dilated congested blood vessels within the tooth (chronic pulpal hyperemia), sensitivity and altered nerve potential. In addition, the pain caused by the injection itself can be one of the most common causes of cooperation lost in children. For these reasons, injecting anesthesia into the bone (intraosseous anesthesia) has recently gained attention in the field of endodontics. These devices like QuickSleeper 5 have started to become more widespread to counteract the disadvantages associated with block anesthesia, which will numb the teeth and also the jaw or lips. However, clinical studies that touch on computerized intraosseous anesthesia devices are generally poor.

The aim of this study is to evaluate the effectiveness, pain caused and complications associated with QuickSleeper 5 and compare it with an injection nerve block in anesthetizing MIH molars in children as there is uncertainty about which is better or if they may be equivalent.

Who can participate?
Cooperative children aged between 6 and 8 years old who need treatment for their first permanent molars with MIH

What does the study involve?
Children who participate in this trial will be exposed to both types of anesthesia (QuickSleeper 5 and an injection nerve block). 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?
Children who participate in this trial will benefit by being anesthetized by two types of anesthesia with the least possible pain. In addition, their lower first permanent molars will be

treated. All children contraindicated to both lidocaine and epinephrine will be excluded, thus there should be no risks when 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?
December 2021 to October 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3166

Study information

Scientific Title
Evaluation of the effectiveness, pain and complications of computerized intraosseous anesthesia in comparison to inferior alveolar nerve block to anesthetize permanent lower first molars with molar incisor hypomineralization in children

Study objectives
1. QuickSleeper 5 is more effective than block anesthesia in anesthetizing mandibular first permanent molars in children with molar incisor hypomineralization (MIH)
2. QuickSleeper 5 causes less pain than block anesthesia while anesthetizing mandibular first permanent molars with MIH
3. QuickSleeper 5 causes fewer complications than block anesthesia after anesthetizing mandibular first permanent molars with MIH

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/01/2022, Ethics scientific committee at Damascus University (Mazzeh Street, Damascus, Syria; +963 9933490577; drsalloum74@hotmail.com), ref: 3166

Study design
Interventional double-blind split-mouth randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Anesthetizing permanent molar incisor hypomineralization molars in children

Interventions
This study is designed to compare two types of dental local anesthesia in children; the intervention type will be QuickSleeper 5 (QS) and the control one will be an active control with an inferior alveolar nerve block (IANB).
The study will include 40 participants aged between 6-8 years and all of them need bilateral vital pulpotomy for permanent mandibular first molars that are affected by MIH 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 - 40 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 he /she 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 permanent 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
Effectiveness of both techniques of anesthesia will be studied during the pulp treatment procedure assessed by measuring the pain caused by the anesthesia using both a subjective method (Simplified Faces Pain Scale S-FPS) while getting access to the tooth immediately after the injection and an objective method (Face – Legs – Activity – Cry – Consolability scale FLACC) during the excavation of coronal pulp during the injection

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

Overall study start date
20/12/2021

Completion date
10/10/2022

Eligibility

Key inclusion criteria
1. Healthy children who don't suffer from any systemic disease
2. Children aged between 6 - 8 years
3. Children who need bilateral vital pulpotomy for mandibular first permanent molars with MIH.
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
8 Years

Sex
Both

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

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
25/07/2022

Date of final enrolment
25/09/2022

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
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Sponsor information

Organisation
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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
01/03/2023

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

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