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Effectiveness of camouflaged syringe in reducing dental anxiety and pain during maxillary local anesthesia in children

Submission date 24/07/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/07/2025	**Overall study status** Completed	
Last Edited 24/07/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Camouflaging is the act of concealing or disguising an object to make it appear less noticeable. It has been proposed as an effective strategy to reduce the visual and psychological threat posed by dental syringes, particularly in children. A syringe with a friendly, non-threatening appearance may help alleviate anxiety and serve as a distraction during injection. However, there remains a limited number of studies investigating the effect of using camouflaged dental syringes, specifically those covered with brightly coloured, animal-shaped sleeves such as crocodiles, on dental fear and anxiety, and how this relates to perceived pain in children. Therefore, the present study aimed to evaluate the effectiveness of a camouflaged dental syringe in reducing dental pain and anxiety during maxillary infiltration anaesthesia in children aged 6–9 years, compared to a conventional syringe.

Who can participate?
Eligible participants were healthy children aged 6 to 9 years requiring dental treatment involving maxillary infiltration local anesthesia. Included participants had no previous dental experience, had not received any sedative or analgesic medication within three hours before the appointment, and demonstrated positive behavior according to the Frankl Behavior Rating Scale.

What does the study involve?
Participants were randomly divided into two groups:
Group 1 (Control Group): Received local anesthesia using the conventional syringe along with the Tell-Show-Do technique (n = 35).
Group 2 (Experimental Group): Received local anesthesia using a camouflaged syringe along with the Tell-Show-Do technique (n = 35).

What are the possible benefits and risks of participating?
Possible benefits are: Performing non-urgent dental treatment in the maxillary arch, such as pulpotomy, serial extraction, and pulpectomy.
Possible risk is: Injection will be painful if the device is not effective.

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

When is the study starting and how long is it expected to run for?
December 2023 and May 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of camouflaged syringe in reducing dental anxiety and pain during maxillary local anesthesia in children aged 6–9 years: a randomized controlled clinical trial

Study objectives
The study aimed to evaluate the effectiveness of a camouflaged dental syringe in reducing dental pain and anxiety during maxillary infiltration anaesthesia in children aged 6–9 years, compared to a conventional syringe

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/03/2023, The Biomedical Research Ethics Committee (Mazzeh, Damascus, -, Syria; +963 992647528; info@damascusuniversity.edu.sy), ref: 2793/2023

Study design
Randomized double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dental pain and anxiety

Interventions
The sample was collected from children who were referred to the Department of Paediatric Dentistry at the Faculty of Dentistry, Damascus University. Participation in the study was openly voluntary, and informed consent was obtained. Before initiating the procedure, each child was asked to express their level of dental anxiety upon sitting in the dental chair by selecting a facial expression that best represented their emotional state, using the FIS.

To record physiological parameters, a pulse oximeter (Alpha, Prolinx GmbH, Düsseldorf, Germany) was placed on the index finger of the left hand. The device was introduced to the child in a child-friendly manner and described as a happiness meter to enhance acceptance and cooperation.

Behavioral management was carried out using the Tell-Show-Do technique to familiarize the child with the components of either the conventional or camouflaged dental syringe, depending on the assigned group. The explanation was delivered using age-appropriate and imaginative language. The conventional syringe (Dental carpule syringe, Dental Laboratorio, china) was described as a magic juice cup in the control group. The camouflaged crocodile-shaped syringe

(CROCODILE CASE FOR CARPULE (3u.), Angelus®, Londrina, Brazil) was introduced as a brave knight carrying magic juice in the experimental group. Following this behavioral intervention, the pulse rate was measured again, and anxiety was reassessed using the same FIS.

The injection site was then dried, and 20% benzocaine topical anesthetic (Iolite, Dharma Research Inc., Florida, United States) was applied with a cotton applicator for one minute. Subsequently, lidocaine 2% with 1:80,000 epinephrine (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam, Korea) was administered via infiltration in the maxillary arch. One minute after the administration of local anesthesia, a third pulse rate measurement was recorded.

Postoperative pain was assessed using the FLACC scale, based on video recordings of the entire procedure. The assessments were conducted by two independent, blinded evaluators who reviewed the recordings. Cohen's Kappa coefficient values of intra-examiner and inter-examiner reliability were >0.8.

Randomisation:
Participants were randomly allocated to the study groups using the website www.randomizer.org. Each participant was assigned a unique random number. Randomization was then performed using block randomization via www.randomization.com, allocating participants equally into two randomly permuted groups of 35 children each, with a 1:1 allocation ratio.
To prevent allocation bias, the randomization sequence was generated prior to the trial by a third person (a researcher not involved in the study). The investigator conducting the procedures met the participants for the first time in the treatment room after registration and group assignment.
This was a double-blind study: both participants and the data analyst were unaware of the group allocations. The children were not informed about their group assignment or the specific aim of the study.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The camouflaged crocodile-shaped syringe (CROCODILE CASE FOR CARPULE (3u.), Angelus®, Londrina, Brazil)

Primary outcome measure
1. Dental anxiety is measured using the Facial Image Scale (FIS) at baseline (before any intervention) and after behavioral management using the Tell-Show-Do technique and introduction to either the camouflaged or conventional syringe, but before administration of topical anesthesia
2. Pulse rate is measured using a finger pulse oximeter at baseline (while seated in the dental chair), after behavioral management and syringe introduction, and one minute after completion of the local anesthetic injection
3. Pain perception is measured using the Face, Legs, Activity, Cry, Consolability (FLACC) scale during the administration of local anesthesia

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
20/02/2023

Completion date
18/05/2024

Eligibility

Key inclusion criteria
1. Healthy children aged 6 to 9 years requiring dental treatment involving maxillary infiltration local anesthesia
2. Children with no previous dental experience
3. Children who had not received any sedative or analgesic medication within three hours before the appointment
4. Children who demonstrated positive behavior according to the Frankl Behavior Rating Scale

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Children unable to communicate effectively
2. Children with physical or cognitive disabilities
3. Uncooperative children exhibiting disruptive behavior
4. Children with acute pulpitis or severe dental abscess
5. Children whose legal guardians refused to provide consent

Date of first enrolment
02/12/2023

Date of final enrolment
02/05/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh
Damascus
Syria
-

Sponsor information

Organisation
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Sponsor type
Government

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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 peer-reviewed journal.

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from mawia95.karkoutly@damascusuniversity.edu.sy, mawiamaherkarkoutly@hotmail.com

The type of data that will be shared: Not currently known
Timing for availability: Upon a reasonable request
Whether consent from participants was required and obtained: Informed consent was obtained

IPD sharing plan summary
Available on request