

The effect of vibration on anxiety and pain during a dental shot in children

Submission date 12/04/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/05/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The most common reasons why people stop going to the dentist are dental insecurity and anxiety. Children who experience extreme discomfort during dental operations are more likely to have behavioral issues during later appointments, requiring more restraint and taking longer. Furthermore, children who are in pain will delay receiving appropriate dental treatment and are more likely to do so in the future. This study aims to evaluate the effect of a vibration-assisted syringe on pain and anxiety in children.

Who can participate?

Healthy children aged 6-10 years

What does the study involve?

Each child undergoes both anesthetic injections (the conventional injection and the vibration-assisted injection) at two separate dental visits 2 weeks apart. Pain and anxiety levels are compared at the two visits.

What are the possible benefits and risks of participating?

The vibration-assisted syringe may cause less pain. There are no known risks.

Where is the study run from?

Damascus University (Syria)

When is the study starting and how long is it expected to run for?

April 2020 to September 2021

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Muhammad Amer Albouni
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

MS994

Study information

Scientific Title

The effect of vibration on anxiety and pain during injections of local anesthesia in children

Study objectives

To evaluate the effect of a vibration-assisted syringe on pain perception in children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/04/2020, Damascus University Rector (Baramkeh, Damascus, Syria; +966 (0)55 506 3806; no email), ref: 994MS

Study design

Randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pain perception during injections of local anesthesia

Interventions

This study is conducted using a split-mouth design. Each child is subjected to both anesthetic injections, the conventional injection and the vibration-assisted injection, at two separate dental visits.

To determine if the vibratory device (Vibraject; Vibraject® MiltexInc LLC., York, PA, USA) is used or not for the first visit the operator selects one of two cards with either the letter V or C printed on (denoting vibration-assisted or conventional) from an opaque bag. To determine the first side (right or left) to be injected the researchers considered the child's chief complaint.

There is no follow up.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Vibraject

Primary outcome(s)

1. Pain measured using the visual analogue score (VAS) at the end of anaesthesia
2. Anxiety measured using the faces anxiety scale (FAS) at the anaesthesia administration time

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

01/09/2021

Eligibility

Key inclusion criteria

1. Medically fit children
2. Required bilateral maxillary dental treatment
3. Positive or definitely positive behavior

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

1. Children suffering from medical illness
2. Cannot comprehend the pain measures
3. Negative or definitely negative behavior

Date of first enrolment

28/04/2021

Date of final enrolment

01/08/2021

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Department of Pediatric Dentistry

Mazzah High Way

Damascus

Syria

22743

Sponsor information

Organisation

Damascus University

ROR

<https://ror.org/03m098d13>

Funder(s)

Funder type

University/education

Funder Name

Damascus University

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Muhammad Amer Albouni (amer93albouni@gmail.com).

IPD sharing plan summary

Available on request