

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

<b>Submission date</b> 12/04/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/05/2021	<b>Condition category</b> 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  
amer93albouni@gmail.com

# Contact information

## Type(s)

Scientific

## Contact name

Dr Muhammad Amer Albouni

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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

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes