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

Submission date
12/04/2021

Recruitment status
No longer recruiting

Registration date
10/05/2021

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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
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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
20/04/2020

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

Age group
Child

Sex
Both

Target number of participants
30

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
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Publication and dissemination plan
After finishing the procedure and writing the article, the researchers are planning to publish (with all results, statistical analysis and some photos) in Damascus University's journal, and many other international journals.

Intention to publish date
01/12/2021

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