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Acceptability of the Wand® local anaesthetic device for young dental patients

Submission date	Recruitment status	[X] Prospectively registered
08/12/2020	Suspended	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/03/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/07/2021	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Local anaesthesia involves numbing an area of the body using a type of medication called a local anaesthetic.
These medications can be used to treat painful conditions, prevent pain during a procedure or operation, or relieve pain after surgery.
Dental injections are used to inject the local anaesthetic to a specific site in the mouth as an essential measure to provide painless dental treatment. However, injection pain is one of the most common reasons for dental anxiety. A computer-controlled local anaesthetic device named the 'Wand®' has recently been developed, designed to reduce the discomfort of providing dental local anaesthesia. The aim of this study is to compare the Wand® and the usual injection method to find which is more acceptable to children.

Who can participate?
Children aged 10 - 16 years who require non-urgent dental treatment under local anaesthetic.

What does the study involve?
Participants will be randomly allocated to receive local anaesthetic by one of two methods.
The intervention group will receive the intervention treatment (dental local anaesthetic via the Wand® CCLAD system), and the control group will receive the control treatment (dental local anaesthetic via the conventional dental syringe).
The two groups will be compared in terms of their acceptability of the LA delivered by the two methods.

What are the possible benefits and risks of participating?
Benefits: The child's dental treatment will be done by experienced dentists at the Eastman Dental Hospital using widely recognised local anaesthetic delivery methods.
Risks: It will take extra time out of the participant's day to complete the questionnaires (15-20 minutes). Otherwise, there are no known risks for children participating in this trial rather that the known risks of the local anaesthetic that will be explained by the child's dentist during the appointment.

Where is the study run from?
UCLH Eastman Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2020 to July 2021

Who is funding the study?
Ministry of Education (Libya)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
184896

Protocol serial number
Sponsor R&D reference: 125424, IRAS 184896

Study information

Scientific Title
Assessing the acceptability of the Wand® computer-controlled local anaesthetic device for paediatric dental patients: A pilot clinical trial

Study objectives
To compare child dental patients' acceptability of local anaesthetic (LA) delivered by the Wand® computer-controlled local anaesthetic delivery system (CCLAD) to LA delivered by the conventional dental syringe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved DATE, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207104 8036; nottingham1.rec@hra.nhs.uk), ref:

Study design
Parallel unblinded randomised controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Assessing Wand® local anaesthetic acceptance in young dental patients

Interventions
Trial procedure:
1- Pre-intervention assessments
Patients will be screened for eligibility against the inclusion criteria for their age (10-16 yrs), their medical history will be checked for any health problems that will interfere with the participation in the trial (ASA Class III or above) and the dental history will be reviewed for any previous experience with the local anaesthetic administrated with the Wand. Patients are required to have no previous experience with the Wand LA in order to be eligible. Participants who are willing to involve will then be consented and explained how to use the modified Visual Analogue Scales VAS before the trial on the same day which will be used by them to assess the LA acceptability during the intervention.

2- Randomisation Procedures
Participants are considered to be enrolled into the trial following consent
All of the enrolled participants will be assigned to either the intervention or control group, with equivalent numbers of anxious and non-anxious in the two groups. Simple randomisation will be used for the allocation. The randomisation will be conducted using envelope technique by the statistician who will have no contact with the participants or researchers. The allocation will only take place after obtaining consents and assents. The researchers will be blinded to which group a participant has been assigned.
As an unblinded pilot trial, participants will not be blinded to which LA delivery method they will receive so that their acceptability of the overall experience will be assessed. The clinical practitioners who will provide the dental treatment including the administration of the LA will not be blinded during the clinical trial as it is not possible. However, outcome assessors will be blinded for measuring the outcomes.

3- Intervention procedures
All enrolled children in this trial will follow a three-phase procedure on the trial day as follows. Data will be recorded by the operator providing the treatment:
• Pre-LA phase: In this stage participants will indicate their prospective acceptability for the

intervention by completing the Children's Intervention Rating Profile (CIRP), following which pre-LA participants' anxiety will be recorded using Children's Experience of Dental Anxiety Measure (CEDAM). It is estimated that this phase will last for 10 minutes.
• LA phase: During this stage the intervention group will receive LA via the Wand whereas the control group will receive LA via the traditional syringe, as a part of their required dental treatment. Treatments will be provided by the same practitioners who ordinarily treat the participants, and who are part of the clinical staff at the hospital. Immediately following the administration of the LA, participants will be given a modified VAS to record their concurrent acceptability of the LA received. Subsequently, the dental treatment will be continued and is estimated to range from 30-60 minutes, depending on the presenting dental complaints of participants. The trial treatments will be applied as a one-off at the Eastman Dental Hospital, and only this visit will be recorded and administered by clinical staff according to a standardised procedure, as blinding will not be feasible. This will be as follows:
o Oral mucosa of the injection site will be dried and a topical anaesthetic, Lignocain 5% (a generic drug), will be applied by a cotton applicator for one minute.
o LA will be performed according to the site of treatment (infiltration or nerve block) using the same LA substance (2% Lidocain with 1:80,000 epinephrine) and quantity for both types of techniques, as well as the gauge and the length of the needle. The conventional dental syringe will be used to deliver LA to control group participants and the WandTM (Milestone Scientific Inc.) will be used to deliver LA to the intervention group, as per the manufacturers' instructions. Both are standard devices used in everyday dental treatment provided in the Hospital.
• Post-LA phase: Similar to the pre-LA phase, the acceptability and the anxiety of the participants to the LA provided will be measured using the same scales, however acceptability in this phase is measured retrospectively. Further, children's fear of dental injections will be measured with Intra-Oral Injection Fear Scale (IOIFs). This stage will last approximately 15 minutes.

-Subsequent assessments and procedures
After the trial visit the trial is complete, and patients will continue with treatment as normal. A schedule of all trial assessments and procedures is as follows:
Visit 0 (baseline): Patients will be assessed against the inclusion criteria when they attend their arranged dental appointment with a member of the clinical staff. This includes, reviewing patients' notes for their age, medical and dental history and for any notes of patients' degree of anxiety, if any. Patient' will then be seen by one of the clinicians and a treatment plan will be determined and only following this, it will be confirmed whether the patient meets the inclusion criteria. Eligible patients will be invited to participate in the trial and will be provided with verbal and written explanation of the trial. They will be advised to respond via email to confirm if they are willing to be involved. Potential participants will then be given a date for their next treatment when they will receive the LA with either the intervention or the control anaesthetic device.
Visit 1 (trial): When participants agree to participate and attend, they will first be assented and their parents/guardians will be consented and only by which their involvement in the trial is commenced. Participants will be handed an intervention procpective acceptability rating profile and an anxiety scale to complete. They will also be explained on how to use the modified VAS that they will be given during the treatment just after having the LA to assess the concurrent acceptability. On the same visit following completion of the dental treatment, Participants will be asked to complete another anxiety scale, to measure the effect of the intervention on the anxiety level, and a retrospective intervention acceptability rating profile. Participants' injection fear will also be recorded after the treatment only to avoid provoking any needle anxiety before the treatment using an injection fear scale. By this point the participant's involvement in the trial comes to an end.
This trial is to be performed unblinded whereby only the researcher (RE) and the supervisors (PA and SP) will not be able to identify the assigned LA delivery method to avoid influencing the

responses. Participants will not be blinded to what LA technique they will receive to enable them to reflect their experience of the whole procedure. The researcher who will collect and analyse data and adjudicate outcome will not be informed of what group were participants assigned to and the two groups will be labelled using nonidentifying terms (A and B).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The Wand® computer-controlled local anaesthetic device

Primary outcome(s)
Measured before and after dental treatment during the single visit:
1. Acceptability of local anaesthetic received using a VAS
2. Level of anxiety before using a novel questionnaire

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
03/07/2021

Eligibility

Key inclusion criteria
1. Paediatric patients aged 10 - 16 years
2. No previous experience of having LA delivered by the Wand®
3. Requiring dental treatment under LA
4. Good general health (American Society of Anaesthesiology ASA classification I & II)
5. Able to understand English sufficiently to complete scales/rating profiles appropriately
6. Patients and guardians willing to give informed assent/consent to participate in the study
7. Co-operative, with no indication of conscious sedation or treatment under general anaesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Aged below 10 or over 16 years old
2. Children unable to understand English sufficiently
3. Requiring treatment under conscious sedation or general anaesthesia
4. Children with ASA class III or over
5. Patients who have previously received dental anaesthesia using the Wand®
6. Unwilling to give consent

Date of first enrolment
01/07/2021

Date of final enrolment
03/07/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCLH Eastman Dental Hospital
Royal National ENT and Eastman Dental Hospitals
47-49 Huntley Street
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Sponsor information

Organisation
Libyan Ministry of Education

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Libya

Alternative Name(s)
Ministry of Education-Libya, Libyan Ministry of Education,

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Libya

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/03/2021	No	Yes
Participant information sheet			10/03/2021	No	Yes
Participant information sheet			10/03/2021	No	Yes
Protocol file	version v3	15/07/2020	10/03/2021	No	No