ISRCTN12547356 https://doi.org/10.1186/ISRCTN12547356

The use of laser doppler flowmetry for the assessment of the tooth vitality following dental trauma in children

Submission date 25/02/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 15/06/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/05/2017	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Teeth injuries are considered one of the most challenging events that occur in dentistry, especially in children. After an injury, there is a possibility that the blood supply to the tooth may become compromised. This, in turn, can lead to the death of the tooth as the tooth pulp is no longer being supplied with blood. Such a tooth is called a non-vital tooth. The conventional tools available to assess the nerves and blood supply to a tooth are not always reliable due to many reasons including cooperation and understanding especially children. Failure to assess how good a blood supply is to the tooth may result in tooth death, weakening it and leaving in vulnerable to removal. The laser doppler flowmetry is a machine that has been used for several years. It is non-invasive and painless and shown to be more reliable than the traditional techniques. However, the current data is based on weak evidence. The aim of this study is to assess the reliability of this machine.

Who can participate?
Children aged 8-16 with a root canal treated non-vital tooth.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (test group) have their teeth vitality assessed using laser doppler flowmetry. Those in group 2 (control) have their teeth sensibility assessed using conventional electrical and thermal (ethyl chloride) pulp tests.

What are the possible benefits and risks of participating?
There are no potential risks. The patient should not experience any pain, discomfort, distress, inconvenience or change to lifestyle. There is no direct benefit to research participants. However, the results from the study may help to benefit future patients when they have dental injuries. We are assessing the use of diagnostic tools in this study regardless of any treatment needs. Any treatment will be provided at Leeds Dental Institute as per local protocols regardless of participation in the study.

Where is the study run from?
Leeds Dental Institute (UK)

When is the study starting and how long is it expected to run for?
May 2015 to July 2017

Who is funding the study?
University of Leeds (UK)

Who is the main contact?
Mr Nahar Ghouth

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The diagnostic accuracy of the laser doppler flowmetry in assessing pulp vitality of traumatised teeth in paediatric patients

Study objectives
1. Alternative hypothesis: Laser doppler flowmetry is more accurate than conventional method in assessing pulpal status of permanent anterior teeth in paediatric patients.
2. Null hypothesis: Laser doppler flowmetry is as accurate as the conventional method in assessing pulpal status of permenant anterior teeth in paediatric patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
RES Committee North West - Greater Manchester East, 08/09/2015, ref: 15/NW/0583

Study design
Parallel-randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
The validation and assessment of the accuracy of laser doppler flowmetry in comparison to conventional pulp sensibility tests (electrical pulp test and ethyl chloride) in assessing pulpal vitality of permanent anterior traumatised teeth in paediatric patients.

Interventions
A parallel-randomised controlled diagnostic trial will be performed. This will involve two groups of patients:
1. Test group where teeth vitality will be assessed using laser doppler flowmetry.
2. Control group where teeth sensibility will be assessed using conventional electrical and thermal (ethyl chloride) pulp tests.

Intervention Type
Device

Primary outcome(s)
1 The sensitivity and specificity of laser Doppler flowmetry, electrical pulp test and ethyl chloride. The number of true positives, false positives, true negatives and false negatives will be calculated for Laser Doppler flowmetry, EPT and Ethyl chloride using the traditional 2X2 table. Based on this, the sensitivity and specificity will be calculated after all the data has been collected.
2. The correct flux threshold below which a tooth could be identified as non vital when using laser Doppler flowmetry. The machine learning technique will be used to obtain the optimal threshold to distinguish vital and non-vital tooth using 50% of the data as training data, and the rest 50% will be used as test data to obtain the sensitivity and specificity of laser Doppler flowmetry

Key secondary outcome(s))
The repeatability and reproducibility of each method. Inter class correlation will be used to measure the repeatability and reliability of all tests.

Completion date
30/07/2017

Eligibility

Key inclusion criteria

1. Children between 8-16 years old.
2. Medically fit (ASA I, II).
3. Understanding of English.
4. Acceptable level of cooperation.
5. Patients able to understand instructions.
6. Children with one non-vital maxillary central or lateral incisor that had a completed root canal treatment with Gutta-Percha and an ideally a contra-lateral non-traumatised vital tooth.
7. The root canal treated tooth should not be tender to percussion and have a periapical radiolucency or a sinus tract.
8. The vital tooth should ideally not have received a dental trauma however should that be the case, the tooth should:
8.1. Have received no severe luxation injuries such as intrusion, lateral luxation, avulsion, or extrusive luxation.
8.2. Have been consistently responsive to EPT and ethyl chloride pulp tests during the past 6 months.
8.3. Should have normal colour.
8.4. Should not be tender to percussion.
8.5. Not show any radiographic signs of loss of vitality
9. All teeth should be minimally restored, covering less than half the labial crown surface.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Medically and mentally compromised children
2. Children with learning disabilities
3. History of moderate and significant behaviour management problems
4. Communication barrier such as not understanding English language
5. Heavily restored teeth covering more than half the labial surface of teeth
6. Patients on routine analgesics, antidepressants or antihypertensive drugs
7. Non-vital teeth treated with regenerative endodontic technique
8. Vital teeth with pulp canal obliteration
9. If the contra lateral vital tooth:
9.1. Had severe luxation injuries such as intrusion, lateral luxation, avulsion, or extrusive luxation
9.2. Has not been consistently responsive to EPT and ethyl chloride pulp tests during the past 6

months
9.3. Is of an abnormal colour
9.4. Is tender to percussion
9.5. Shows any radiographic signs of loss of vitality

Date of first enrolment
01/05/2015

Date of final enrolment
30/07/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Dental Institute
Clarendon Way
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
University of Leeds, Leeds Dental Institute

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University Of Leeds

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes