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The use of speckle contrast imaging technique to assess pulpal blood flow

Submission date
11/04/2016

Registration date
25/05/2016

Last Edited
18/05/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Oral Health

✓ Prospectively registered
? Protocol not yet added
? SAP not yet added
? Results not yet added and study completed for more than 1 year
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Teeth injuries are considered one of the most challenging events that occur in dentistry, especially in children. After an injury, it is possible that the blood supply to the tooth may become affected and compromised leading to death of the nerves and blood vessels in the tooth, and therefore of the tooth itself. Once a tooth is dead, it is described as non-vital. The conventional diagnostic tools available to assess tooth nerve/blood supply are not always reliable. Child cooperation and understanding contribute greatly to this shortfall. Failure to assess the vitality of the tooth (that is, failure to assess whether the tooth is still alive) may result in de-vitalising a normal tooth (that is, saying a tooth is dead when it is not) which may render the tooth weak for the suturing (stitching) and possibly losing the tooth. A new non-invasive, non-patient contact, entirely safe and painless laser speckle contrast imaging technique has been developed. It is a method which visualizes tissue blood supply in the microcirculation (tiny blood vessels) instantaneously using a camera. It would be an excellent diagnostic tool for use detect the blood flow in the dental pulp. As a result, this study will look at testing this machine when used to assess the feasibility of recording blood flow in teeth.

Who can participate?
Children aged between 8-16 with one non-vital tooth and – preferably, a matching live (vital) tooth.

What does the study involve?
The blood flow of one non-vital and one vital tooth is tested in each patient using the laser speckle contrast imaging technique. The results are then used to assess the accuracy and reliability of the new machine.

What are the possible benefits and risks of participating?
There are no direct benefits or risks associated with taking part 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?
September 2016 to January 2017

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

Who is the main contact?
Mr Nahar Ghouth

Contact information

Type(s)
Scientific

Contact name
Mr Nahar Ghouth

ORCID ID
http://orcid.org/0000-0003-1184-6864

Contact details
School of Dentistry
University of Leeds
Leeds
United Kingdom
LS16 5RU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
V5

Study information

Scientific Title
Assessment of blood supply to permanent teeth in children using the laser speckle contrast imaging technique : a pilot feasibility study

Study hypothesis
There is no significant difference between the flux values of the vital and non vital teeth when using laser speckle contrast imaging technique when assessing pulpal blood flow in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Diagnostic cross sectional

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Condition
Blood supply to tooth pulp

Interventions
The blood flow of one non-vital and one vital tooth will be tested in each patient.

Intervention Type
Device

Primary outcome measure
The FLUX value for the pulpal blood flow.It will be measured for a vital tooth and non vital tooth at a single time point only.After which, a statistical ratio is calculated to get the sensitivity /specificity.

Secondary outcome measures
1. Repeatability of the machine will be calculated using FLUX values.
2. A second measurement on 20% of the sample size will be done to calculate the reliability by comparing FLUX values.

Overall study start date
01/09/2016

Overall study end date
01/01/2017

Eligibility

Participant inclusion criteria
1. Children between 8-16 years old
2. Medically fit (ASA I)
3. Children with one non-vital maxillary central or lateral incisor that had a completed root canal treatment or pulp extirpation, and an ideally a contra-lateral non-traumatised vital tooth
4. The non-vital tooth should not be tender to percussion or have periapical radiolucency or a sinus tract

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
30

Participant exclusion criteria
1. Heavily restored teeth covering more than half the labial surface of teeth
2. Non-vital teeth treated with regenerative endodontic technique
3. Vital teeth with pulp canal obliteration

Recruitment start date
01/09/2016

Recruitment end date
01/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Dental Institute
Clarendon Way
Leeds

United Kingdom
LS16 5RU

Sponsor information

Organisation
Leeds Dental Institute

Sponsor details
Clarendon Way
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
University/education

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

Publication and dissemination plan
The study results will be published in a peer review article.

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available