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

Submission date 11/04/2016	Recruitment status No longer recruiting	[X] Prospectively registered
		[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
25/05/2016	Completed	[_] Results
Last Edited	Condition category	Individual participant data
18/05/2016	Oral Health	[_] 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, 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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 objectives

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

Health condition(s) or problem(s) studied 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

Completion date 01/01/2017

Eligibility

Key inclusion criteria

1. Children between 8-16 years old

2. Medically fit (ASA I)

 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
 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

Key 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

Date of first enrolment

01/09/2016

Date of final enrolment 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