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Cone beam computed tomography study to assess endodontic disease

Submission date
28/01/2018

Recruitment status
No longer recruiting

Registration date
07/02/2018

Overall study status
Completed

Last Edited
05/02/2018

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
Dental radiographs (X rays) are usually taken immediately after completion of root canal treatment and on a periodic basis (review appointments), usually after 1 and 2 years after treatment has been completed, to assess how successful treatment has been. The amount of information gained from conventional dental radiographs is limited as the images produced are only 2 dimensional (like a photograph). A 3-dimensional scan called a Cone Beam Computed Tomography (CBCT) scan is the latest technology for imaging teeth. It allows the tooth to be assessed in 3-dimensions and therefore potentially provides more useful information including the degree of healing. This CBCT scan may provide a better understanding of the anatomy of the tooth before carrying out root canal treatment. The aim of this study is to compare 2D radiographs and 3D CBCT scans to find out whether this new 3D scanning technique is more accurate and helpful in assessing healing of root canal treatment.

Who can participate?
Healthy volunteers, over 18 years old

What does the study involve?
Immediately before root canal treatment is started, an additional 3D CBCT scan of the tooth is taken in addition to the conventional 2D radiograph. The additional scan takes 5-10 minutes to carry out. Review appointments are arranged 1 and 2 years after the end of the root canal treatment to assess the healing of the tooth. If the degree of healing is uncertain at this time, an additional review and scan may be required 4 years after the end of the treatment. However, this is not common. In some instances, only a deep filling may be required either on its own (i.e. no root canal treatment), or together with root canal treatment to manage the root canal problem. When indicated, there may be no active treatment apart from periodic review appointments as described. In addition to using the inbuilt CBCT software, additional third party software may also be used to assess the anatomy of the tooth in anticipation of gaining further information about the tooth which may in turn help to treat the tooth more efficiently and effectively.

What are the possible benefits and risks of participating?
CBCT may allow dentists to accurately assess whether treatment has been successful. The

additional radiation dose from the second scan is minimal and is very similar to the conventional radiograph. The chance of any harm occurring as a result of exposure to dental X ray radiation is very small. The effective dose of each of these cone beam computed scans is equivalent to 3-4 days of annual background radiation, so for the whole study the extra scans are equivalent to less than 10 days of background radiation. To put this in perspective, the effective dose from cosmic radiation on board an aircraft flying a round trip from Paris to Tokyo is equivalent to 15 days of annual background radiation.

Where is the study run from?
1. Endodontic PG unit, Guy's & St Thomas' NHS Foundation Trust, London, UK
2. Dr Shanon Patel, 45 Wimpole Street, London, UK

When is the study starting and how long is it expected to run for?
September 2015 to August 2018

Who is funding the study?
Kings College London (UK)

Who is the main contact?
Dr Shanon Patel

Contact information

Type(s)
Public

Contact name
Dr Shanon Patel

Contact details
Endodontic Postgraduate Unit
Floor 25 Guy’s Tower
Guy’s Hospital
London
United Kingdom
SE1 9RT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REC 08/h0804/79

Study information

Scientific Title
Prospective clinical trials to determine the impact of various treatments on the outcome of endodontic disease assessed with cone beam computed tomography

Study objectives
Cone beam computed tomography (CBCT) is more sensitive than periapical radiographs in determining outcome of treatment. Radiographic signs of healing will be identified earlier with CBCT. Teeth with signs of complete healing on conventional radiographs may still have radiographic signs of endodontic disease when assessed with CBCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bridge Research Ethics Committee, 14/09/2015, ref: 08/H0804/79

Study design
Prospective multicentre clinical study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Endodontic disease

Interventions
Immediately before root canal treatment is commenced in addition to the conventional radiograph a CBCT scan is carried out. Review appointments will also be arranged 1 and 2 years after the completion of root canal treatment to assess the healing of the tooth. If the degree of healing is uncertain at this time, an additional review and scan may be required 4 years after completion of treatment. In addition to using the inbuilt CBCT software, an additional third party software may also be used to assess the anatomy of the tooth.

Intervention Type
Other

Primary outcome measure

Clinical and radiographic signs of healing, assessed using recognised outcome criteria (Patel et al., 2012) at 1 and 2 years post treatment

Secondary outcome measures
Operator stress levels during treatment, measured at the end of treatment

Overall study start date
14/09/2015

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Adults (over 18) who are able give verbal and written consent
2. Not pregnant
3. Not immunocompromised

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Children (<18 years old)
2. Pregnant patients
3. Immunocompromised
4. Existing advanced gum disease

Date of first enrolment
01/01/2016

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's & St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 9RT

Study participating centre
Shanon Patel
45 Wimpole Street
London
United Kingdom
W1G 8SB

Sponsor information

Organisation
NHS Health Research Authority, London Bridge Research Ethics Committee

Sponsor details
Skipton House
80 London Road
London
United Kingdom
SE1 6LH

Sponsor type
Research organisation

Funder(s)

Funder type
University/education

Funder Name
Kings College London

Alternative Name(s)

King's College, King's College London UK, KCL, King's

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high impact dental journals.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date