Cone beam computed tomography study to assess endodontic disease

Submission date	Recruitment status	Prospectively registered
28/01/2018	No longer recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
07/02/2018	Completed	Results
Last Edited	Condition category	Individual participant data
05/02/2018	Oral Health	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

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s))

Operator stress levels during treatment, measured at the end of treatment

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

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

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

Study outputs

Output type

Details

Date created Date added Peer reviewed? Patient-facing?