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Understanding the factors that affect clinical outcomes (such as tooth survival and apical healing) following non-surgical or surgical root canal treatment

Submission date
15/06/2018

Recruitment status
No longer recruiting

Registration date
28/06/2018

Overall study status
Completed

Last Edited
28/06/2018

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
Root canal treatment is the procedure used to get rid of the bacteria present in the root canal system that cause inflammation or abscesses in the tissue around the end of the tooth where it fits into the jaw. The treatment involves drilling out of the canal space to allow thorough rinsing with a disinfecting solution to kill the bacteria. However, the best method of doing this is not known.
This study aims to identify the factors associated with good or poor tooth survival after root canal treatment by examining patient notes and X-rays from annual dentist visits. This will help dentists to choose the best ways of performing root canal treatment.

Who can participate?
1500 men or women aged over 16 years who are scheduled for root canal treatment or retreatment in the Department of Endodontics, Eastman Dental Hospital, UCLH.

What does the study involve?
Study participants will attend two appointments, with a 7-day interval, for routine root canal treatment or retreatment by one of the clinicians in the Endodontics Department. They will receive treatment as usual. The study will analyse information related to the pre-treatment condition of the tooth, details of the treatment, and condition of the tooth at each follow-up appointment from the patients' dental records.

What are the possible benefits and risks of participating?
Participants will receive treatment as usual. There is no direct benefit to the participating patients, but the information obtained may help improving the treatment of future patients suffering from the same condition. Participation in the study will not involve any disadvantages or additional risks.

Where is the study run from?
This study will take place at the Eastman Dental Hospital, UCLH, London, UK.

When is the study starting and how long is it expected to run for?
December 1995 to January 2023

Who is funding the study?
This study is self-funded. Clinical activities were carried out at the premises and under the sponsorship of Eastman Dental Hospital, UCLH.

Who is the main contact?
Professor Kishor Gulabivala
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective evaluation of the individual and interactive influence of pre-operative, intra-operative and post-operative factors on the outcome of endodontic treatment procedures

Study objectives
To assess the survival probability and prognostic factors for periodontally involved teeth with advanced attachment loss managed by periodontal and root canal treatment, with or without root amputation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Research & Ethics Committee of UCL Hospitals NHS Trust, registered 06/12/1995, 96/E195. No formal ethics approval was required because the study only involved extraction of the data from clinical notes.

Study design
Observational longitudinal study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Advanced periodontal disease

Interventions
The participants attend routine root canal treatment appointments and subsequent routine annual follow-ups for 4 years post-operatively. They only consent for donation of routine clinical data for the study.

Intervention Type
Other

Primary outcome measure
Tooth survival assessed using tooth extraction information provided by patients, referring dentists or notes in patients' records. The duration of follow-up was annually up to 4 years post-treatment.

Secondary outcome measures
Periapical healing assessed using pain or swelling indicating periapical health based on clinical and radiographic examination. The duration of follow-up was annually up to 4 years post-treatment.

Overall study start date
06/12/1995

Completion date
01/01/2023

Eligibility

Key inclusion criteria
1. With teeth that exhibited 5 mm or more clinical attachment loss or furcation involvement
2. With teeth that had undergone non-surgical periodontal debridement
3. Had undergone elective non-surgical root canal treatment prior to root amputation, or root canal treatment for management of concomitant pulpal or periapical pathosis followed by surgical periodontal debridement after being diagnosed as a “perio-endo” problem

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
112

Key exclusion criteria
1. With teeth with incomplete periodontal or root canal treatment data
2. With teeth with incomplete root canal treatment

Date of first enrolment
01/04/1996

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eastman Dental Hospital, UCLH
256 Gray's Inn Road
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WC1X 8LD

Sponsor information

Organisation
Eastman Dental Institute, University College London

Sponsor details
256 Grays Inn Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Not defined

Funder Name
self funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2024

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