

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/06/2018	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Dr Yuan-Ling Ng

Contact details

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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

London

United Kingdom

WC1X 8LD

Sponsor information

Organisation

Eastman Dental Institute, University College London

Sponsor details

256 Grays Inn Road
London
England
United Kingdom
WC1X 8LD

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