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Effects of root canal treatment with or without manual-dynamic irrigation on post-operative pain and periapical healing

Submission date 22/05/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/06/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/10/2020	**Condition category** Oral Health	[_] 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 swelling in the area around the end of the tooth. One of the most important steps is to use antibacterial liquids to help wash/scrub the canal surfaces and to kill the bacteria. In both initial treatment and re-treatment, getting rid of the bacteria is difficult, especially at the end of the root canal. In order to enhance the cleaning at the end of the canal, we gently pump (agitate) the antibacterial liquids inside the root canal using small rubber points (gutta-percha point). This treatment procedure has recently been widely adopted by doctors. However, there is no evidence on the frequency and intensity of pain experienced following the procedure as well as on the long-term effect of treatment to support the use of this method. This study is therefore being carried out to compare whether post-treatment pain would occur more often and, if so, if the pain is more severe following root canal treatment with supplementary pumping of the antibacterial solution using a rubber cone.

Who can participate?
Adult men and women, scheduled for root canal treatment or retreatment in the Department of Endodontics, Eastman Dental Hospital, UCLH

What does the study involve?
Study participants attend two appointments, with a 7-day interval, for root canal treatment or retreatment by one of the 10 trained research doctors. The method for canal irrigation (passive versus manual-dynamic) for each patient is allocated through a process called randomisation which is like tossing a coin. After each treatment session, the participants complete a questionnaire reporting their pain experience over 3 days after the operation. Following completion of treatment, the participants are monitored for 1 year to assess the healing of the tissue around the end of the tooth. At the end of the study, the incidence and intensity of the pain after the operation reported by the patients, as well as the probability of healing after treatment, are compared in the two treatment groups. Participants are involved in this study for

a period of about 13 months (one month during treatment plus 12 months after treatment completed). However, patients are reviewed at the Endodontics Review Clinic as per department protocol for 4 years to monitor the long-term outcome of the root canal treatment.

What are the possible benefits and risks of participating?
There is no direct benefit to the participating patients, but the information obtained may help improve the treatment of future patients suffering from the same condition. Participation in the study will not have any disadvantages or risks. The patient may experience some discomfort which may be encountered during normal root canal treatment/retreatment procedures; this includes mild discomfort for 12-24 hours after the operation as a result of maintaining an open mouth, local anaesthesia and routine root canal treatment procedures.

Where is the study run from?
Eastman Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2014 to September 2015

Who is funding the study?
UCL/UCLH NHS Foundation Trust (UK)

Who is the main contact?
Dr Yuan-Ling Ng

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14/0014

Study information

Scientific Title
Long-term outcome and post-operative pain associated with chemo-mechanical root canal debridement using a manual-dynamic irrigation protocol in teeth associated with apical periodontitis: a randomised controlled trial

Study objectives
It is hypothesized that the use of a rubber point for agitation of the antibacterial solution (GP pumping) during root canal treatment will significantly increase the incidence of post-operative pain and the probability of periapical healing in comparison to delivery of the antibacterial solution passively (passive irrigation). The null hypothesis is that there is no significant difference in the incidence of post-operative pain and probability of periapical healing between the two treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Hampstead, 13/03/2014, ref. 14/LO/0265 (IRAS project ID: 135809)

Study design
Randomised double-blinded parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Apical periodontitis

Interventions
The intervention treatment is called manual-dynamic irrigation and the control treatment is called passive irrigation. Manual-dynamic irrigation involved using a syringe and needle to deliver the antibacterial solution (irrigant) into the root canal during treatment and supplemented with pumping (agitation) of the irrigant using a rubber (gutta-percha) point. Passive irrigation involved using a syringe and needle to deliver the antibacterial solution into the root canal without any agitation of the irrigant.

Intervention Type
Procedure/Surgery

Primary outcome measure
The pain experienced at 12-24, 24-48, 48-72 hours after each root canal treatment visit will be measured using a Visual Analogue Scale score (0 = no pain; 10 = worst patient imaginable)

Secondary outcome measures
Periapical healing at 12 months after completion of the root canal treatment will be judged to be successful if there is absence of clinical (pain, swelling, presence of a 'gum boil') or radiographic (dark area around the root) signs of disease at follow-up

Overall study start date
15/04/2014

Completion date
15/09/2015

Eligibility

Key inclusion criteria
Those patients on the waiting list for non-surgical root canal treatment or root canal retreatment in the Department of Endodontics, Eastman Dental Hospital, London, UK and fulfilling the following inclusion criteria (based on the notes from the New Patient Consultation Clinic and findings from the pre-treatment assessment session) will be invited to participate.
1. Age 18 years or older
2. Absence of history of diabetes and/or a medical condition which requires long-term steroid or anti-inflammatory/analgesic medication
3. Absence of history of chronic orofacial pain, major traumatic injuries, or major maxillo-facial surgery
4. Absence of persistent or spontaneous pre-operative pain at New Patient Clinic
5. Able to attend two consecutive appointments for treatment to be completed within 1 month
6. The teeth should be permanent with mature apex (apices)
7. The teeth should have a non-vital pulp (negative response to pulp testing) and associated with a periapical radiolucency observable on a periapical radiograph
8. In cases of teeth requiring root canal retreatment, the predicted treatment complexity should be low based on radiographic examination. The features include:
8.1. Less than 15° canal curvature
8.2. The root canal system anatomy minimally altered by previous treatment
8.3. Only gutta-percha filling present in the root canal
8.4. Low density of previous root filling
8.5. Root filling material confined within the root canal limits
8.6. Absence of procedural errors
8.7. Previous apical surgery not evident
9. Teeth should have been deemed restorable without the need for intra-radicular retention for the final restoration, and have sufficient tooth structure to allow an adequate form of temporization (capable of providing a barrier against leakage during treatment and/or between appointments)

10. The teeth should not be associated with active periodontal disease
11. The teeth and root apices should not be in proximity (less than 1 mm on a periapical radiograph) to the maxillary sinus, inferior dental nerve or the mental foramen

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300 patients

Key exclusion criteria
1. Pregnant patients
2. Patients without a good understanding of the verbal explanations or written information given in English, as well as patients with special communication needs (in view of the descriptive nature of this self-funded Master student research project, there is insufficient funding to support the cost for translation services and validation of consent form information sheets, questionnaires)
3. Teeth with observable cracks or suspicion of root fracture
4. Teeth in which mechanical patency could not be achieved at the apical terminus of at least one canal

Date of first enrolment
15/04/2014

Date of final enrolment
15/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UCL Eastman Dental Institute
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Sponsor information

Organisation
University College London/UCLH NHS Foundation Trust (UK)

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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
UCL/UCLH NHS Foundation Trust (UK), UCL Project ID: 14/0014

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No