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Improving the success rate of apicectomies by using Mineral Trioxide Aggregate

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/12/2008	Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
REC00096

Study information

Scientific Title

Study objectives
The aim of the project is to improve the success rate of apicectomy with root-end filing, a procedure used to manage teeth for which root canal treatment has failed, resulting in continued alveolar infection. This is a widespread form of treatment. The success rate reported in a number of studies is little better than chance. Intensive research in the last 5 years has indicated the mechanisms of failure of this treatment, and potential ways to avoid it. Too often infection remains inside the tooth. Treatment techniques have been modified to clean the tooth better and to reduce communication between the inside of the tooth and the body tissues. There is a need to investigate the success rate of the modified procedure in patients to see if it fulfils the initial results of the laboratory research.
It is planned to recruit patients who require apicectomy according to specific criteria of indication. A total of 320 patients will be randomly allocated to two groups; the control group will have root-end resection with minimal bevelling followed by ultrasonic cavity preparation, and then filling with what is now the current material, IRM; the experimental group will have similar treatment except that the filling material will be the newly developed Mineral Trioxide Aggregate (MTA). The MTA has very good sealing properties and biocompatibility. The teeth will be reviewed at 1 and 2 years post-operatively for clinical and radiological signs of healing or failure, according to specific criteria. The proportions of teeth successful in the two groups will be compared using statistical methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Oral health/stomatognathic diseases: Oral health/stomatognathic diseases

Interventions
1. (Experimental group) root-end resection with minimal bevelling followed by ultrasonic cavity preparation, and the filling material will be the newly developed Mineral Trioxide Aggregate (MTA).
2. (Control group) root-end resection with minimal bevelling followed by ultrasonic cavity preparation, and then filling with what is now the current material, intermediate restorative material (IRM).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
External assessment of degree of healing observed in post-operative radiographs.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/1997

Completion date
01/06/2002

Eligibility

Key inclusion criteria
Adult patients who are referred to Guy's Hospital for apicectomy will be invited to participate. The entry criteria will be that the tooth has apical periodontitis, the tooth could not be adequately and better managed by root canal retreatment, the tooth has an adequate root canal filling, the crown of the tooth is adequately restored, and periodontal probing depths <4 mm except for a unilocular sinus tract.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
320

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/1997

Date of final enrolment
01/06/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UMDS
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
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+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name
NHS Executive London (UK)

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?
Results article	results	01/08/2003		Yes	No