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The efficacy of different local anaesthetic solutions/techniques in patients suffering 'hot' maxillary tooth pulps

Submission date 13/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/11/2005	**Overall study status** Completed	
Last Edited 05/07/2018	**Condition category** 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

05/Q0905/12

Study information

Scientific Title
The efficacy of different local anaesthetic solutions/techniques in patients suffering 'hot' maxillary tooth pulps

Study objectives
The null hypothesis: Pulpal anaesthesia in a maxillary permanent tooth with irreversible pulpitis is no more effective or pain-free following infiltrations of lidocaine or articaine.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Irreversible and reversible pulpitis teeth

Interventions
The power calculation revealed that a sample size using 50 volunteer patients in each supplementary technique (three arms) will have 80% power to detect an effect size of 0.57 in a continuous outcome measure assuming a significance level of 5%. When a buccal infiltration and /or a palatine injection fail to secure pulp anaesthesia, patients will be randomised to receive one of three supplementary injections (three arms) as follows:
1. Repeat infiltration injection with 2% lidocaine with 1:80,000 epinephrine
2. Intraligamentary injection with 2% lidocaine with 1:80,000 epinephrine
3. Intraosseous injection with 2% lidocaine with 1:80,000 epinephrine

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To evaluate the efficacy of maxillary infiltration anaesthesia with articaine and lidocaine (both with epinephrine) in patients suffering from irreversible pulpitis in a maxillary permanent tooth.

Secondary outcome measures
To evaluate the efficacy of supplementary injections such as palatine injections, repeat infiltration, intraligamentary, or intraosseous anaesthesia for securing pain control in patients suffering from maxillary irreversible pulpitis tooth.

Overall study start date
28/06/2005

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. 16 years of age and over
2. Good medical health
3. Any maxillary tooth with irreversible pulpitis and an asymptomatic vital tooth on the opposite site of the arch to act as an internal control of pulp tester function

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
800

Key exclusion criteria
1. Allergies or sensitivities to amide-type local anaesthetics or other ingredients in the anaesthetic solutions
2. Inability to provide informed consent
3. Relevant medical history, which may compromise the welfare of the patient (e.g. unstable angina) or which may compromise data collection (e.g. facial paraesthesia)

Date of first enrolment
28/06/2005

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4BW

Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Student fees

Funder Name
Support services from NHS

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	01/04/2006		Yes	No