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The efficacy of different local anaesthetic solutions/techniques in producing painless sensation in patients suffering 'hot' mandibular tooth pulps

Submission date
13/09/2005

Recruitment status
No longer recruiting

Registration date
11/11/2005

Overall study status
Completed

Last Edited
28/10/2010

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
05/Q0906/21

Study information

Scientific Title

Study objectives
The null hypothesis: Supplementary repeat inferior alveolar nerve block (IANB), local infiltration, intraligamentary injection and intraosseous injection after failed IANB are equally effective and pain free in securing anaesthesia for the pulps of irreversibly pulpitic mandibular teeth.

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

Study type(s)
Treatment

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

Interventions
The power calculation revealed that a sample size using 50 volunteer patients in each supplementary technique (four 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 an initial inferior alveolar nerve block injection (IANB) fails to secure pulp anaesthesia, patients will be randomised to receive one of four supplementary injections (four arms), namely:
1. Repeat IANB 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
4. Local infiltration with 4% articaine with 1:100,000 epinephrine

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
To evaluate the effectiveness of initial IANB in profoundly anaesthetising irreversibly pulpitic and adjacent non-pulpitic.

Key secondary outcome(s))
To evaluate the effect of supplementary local anaesthetic techniques after failure of pulp anaesthesia by IANB in patients suffering mandibular irreversible pulpitis.

Completion date
30/06/2007

Eligibility

Key inclusion criteria
1. Patients of 16 years of age and over
2. Any mandibular 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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with allergies or sensitivities to lidocaine/articaine or other ingredients in the anaesthetic solution
2. Patients who are unable 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
27/06/2005

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Dental Sciences
Newcastle
United Kingdom
NE2 4BW

Sponsor information

Organisation
The Newcastle Upon Tyne Hospitals NHS Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Student fees

Funder Name
Support services from NHS

Results and Publications

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