

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	☐ Prospectively registered ☐ Protocol
Registration date 11/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/10/2010	Condition category Oral Health	☐ 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

Primary study design

Interventional

Study design

Randomised controlled trial

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