

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

<b>Submission date</b> 13/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/10/2010	<b>Condition category</b> Oral Health	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

### 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 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 measure**

To evaluate the effectiveness of initial IANB in profoundly anaesthetising irreversibly pulpitic and adjacent non-pulpitic.

**Secondary outcome measures**

To evaluate the effect of supplementary local anaesthetic techniques after failure of pulp anaesthesia by IANB in patients suffering mandibular irreversible pulpitis.

**Overall study start date**

27/06/2005

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

500

**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**

England

United Kingdom

### **Study participating centre**

**School of Dental Sciences**

Newcastle

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?
<a href="#">Results article</a>	results	01/04/2006		Yes	No