

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

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<b>Registration date</b> 11/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/07/2018	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr John Gerard Meechan

**Contact details**  
Newcastle University  
School of Dental Sciences  
Framlington Place  
Newcastle upon Tyne  
United Kingdom  
NE2 4BW  
+44 (0)191 222 82 92  
j.g.meechan@ncl.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## 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

Room 3.037

Royal Victoria Infirmary

Queen Victoria Road

Newcastle Upon Tyne

England

United Kingdom

NE1 4LP

+44 (0)191 232 5131

jane.varey@nuth.northy.nhs.uk

## 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