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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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# Additional identifiers

**Protocol serial number** 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

#### Study type(s)

Treatment

#### 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(s)

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.

#### Key secondary outcome(s))

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.

#### Completion date

# **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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

**United Kingdom** 

England

## Study participating centre Newcastle University

Newcastle upon Tyne 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