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# Efficacy of articaine infiltration for pulp anaesthesia in adult mandibular teeth

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 27/02/2009 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 08/04/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 24/01/2013 | Oral Health | |

**Plain English summary of protocol**

Background and study aims.
This study in healthy volunteers was designed to test different methods of numbing up teeth in the bottom jaw. Teeth in the bottom jaw are normally numbed up by placing an injection of a solution known as a local anaesthetic at the back of the mouth. This numbs all the teeth on that side of the lower jaw. This method is technique-sensitive and does not always provide numbness of all the teeth. This is often because the target site for the injection is not in the same place in every patient. Unfortunately the desired target is not visible to the naked eye and relies on landmarks that vary between individuals. In this study we were investigating a simpler method of numbing up lower teeth by injecting the local anaesthetic into the gum beside the tooth to be treated. This is a much simpler method than the traditional technique but is not often used as it has been shown to have poor success with the traditional local anaesthetics used in dentistry. We have shown in earlier investigations that the most recently introduced local anaesthetic in dentistry (a drug known as articaine) can be effective in the lower jaw when injected next to the tooth to be treated.
In this study we wanted to test a number of things. Firstly, we wanted to see if it mattered on which side of the tooth the gum was injected (the tongue side or the cheek side). Secondly, we wanted to see if teeth further away from the point of injection were also numbed up.

Who can participate?
Anyone over 18 years of age with sufficient sound teeth in the lower jaw and in good general health could participate.

What does the study involve?
We injected at three different points at different stages of the study. One point was into the gum on the cheek side next to a back tooth, we did a similar thing next to a front tooth. The third point of injection was into the gum on the tongue side of a back tooth. The effect of the injections was determined by testing the teeth by a machine that transmits little electrical impulses to the tooth. The patient cannot feel these impulses when the tooth is properly numb. We tested the numbness of a number of teeth in the lower jaw (close to and distant from the point of injection) for 45 minutes after the injection of the local anaesthetic.

What are the possible benefits and risks of participating?
There was no direct benefit from participating however the results were used to inform dental practice. Minor bleeding and a feeling of prolonged numbness were potential risks of participation.

Where is the study run from?
Newcastle University

When is the study starting and how long is it expected to run for?
The study started in March 2009 and ended in September 2009.

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Dr John Meechan
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### Protocol serial number
4805 version 1

# Study information

### Scientific Title
Efficacy of articaine infiltration for pulp anaesthesia in adult mandibular teeth: a randomised double-blind cross-over study

### Study objectives
1. To determine the efficacy of articaine buccal infiltration in the molar region alone for pulp anaesthesia in mandibular first and second molars, premolars and central and lateral incisors
2. To investigate the efficacy of articaine lingual infiltration in the molar region alone for pulp

anaesthesia in the same teeth
3. To investigate the effect of bilateral articaine buccal infiltrations in the mandibular first molar regions on pulp anaesthesia in the same teeth
4. To investigate the spread of local anaesthetic solution posteriorly after articaine infiltration in the mandibular central incisor region

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
A favourable ethical opinion was given for this study by Newcastle and North Tyneside 2 Research Ethics Committee on the 26th February 2009 (ref: 09/H0907/4)

## Study design
Randomised double-blind cross-over study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Pulp anaesthesia in adult mandibular teeth

## Interventions
1. Local anaesthetics, average number per participant one injection per visit, average time taken five minutes. All injections will be given by an experienced dentist.
2. Electeric pulp testing: electronic pulp testing of the test teeth will be performed by an experienced dentist trained in the method, 73 per visit average time taken one hour
3. Other questionnaire which is completion of visual analogue scales (one each visit) to record injection discomfort. Average number per participant is four and average time taken is one minute.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
Numbness of lower anterior and posterior teeth (front and back teeth) following local anaesthetic injection; measured from one minute after the injection of local anaesthetic solution until 47 minutes.

## Key secondary outcome(s))
Injection discomfort (recorded immediately after injection) and duration of numbness after injection of anaesthetic solution (measured from one minutes after injection until 47 minutes).

## Completion date
01/09/2009

# Eligibility

### Key inclusion criteria
1. Healthy adult volunteers (aged 18 years or older, either sex)
2. Staff or students at Newcastle University

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
The volunteer:
1. Individuals under 18 years old
2. Systemic disorders which may place volunteers at risk from local anaesthetic injection for example bleeding disorders, history of infective endocarditis, pregnant women
3. Allergies to local anaesthetic drugs
4. Facial anaesthesia or paraesthesia
5. In dental pain at the time of the trial
6. Individuals unable to give informed consent

The teeth to be included:
1. Teeth which respond negatively to baseline pulp testing
2. Key test teeth missing

### Date of first enrolment
01/03/2009

### Date of final enrolment
01/09/2009

# Locations

### Countries of recruitment
United Kingdom

England

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

# Sponsor information

**Organisation**
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

**ROR**
https://ror.org/05p40t847

# Funder(s)

**Funder type**
Government

**Funder Name**
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

# 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 | 01/07/2011 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |