

# How do dental injections make your lower teeth go numb?

<b>Submission date</b> 09/02/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/04/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/08/2015	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In this study we would like determine the mode of action of a local anaesthetic technique used to make the lower molar teeth numb. The local anaesthetic medicine to be used is articaine with adrenaline, a medicine commonly used by dentists.

### Who can participate?

Healthy adult volunteers aged 18-30.

### What does the study involve?

The volunteers must attend for three visits, at least 1 week apart. At each visit they will receive two injections, one of which will contain the medicine and the other a needle penetration only with no injection of medicine. This is so they cannot guess what anaesthetic treatment they are receiving. No more than 2 ml of medicine will be injected at each visit, which is a typical amount injected during routine dental treatment and is extremely safe. The medicine will be injected into the gum next to three teeth - the canine, first molar and second molar teeth in the lower jaw, using a standard dental syringe. After each needle penetration they will be asked to rate their discomfort. To test how numb each of five teeth in the lower jaw have become they will be tested with an 'electronic pulp tester', a standard device for assessing numbness of teeth. Each test will be repeated every 4 minutes for 47 minutes following the injections. We will also test some of their unaffected teeth to make sure the testing device is working properly.

### What are the possible benefits and risks of participating?

Some discomfort may be experienced during the injections, the volunteers may find the feeling of numbness unpleasant and they may experience some minor bleeding into their mouth from the injection sites. They should also take care following the injection whilst the numbness is present to avoid any self-inflicted injury. Adverse reactions to the local anaesthetic are very rare but may include headache, swelling or a 'pins and needles' sensation once the numbness has worn off, but these are short lived and will resolve without any treatment.

### Where is the study run from?

Newcastle Dental Hospital (UK).

When is the study starting and how long is it expected to run for?  
February to July 2012.

Who is funding the study?  
The study is funded by 3M ESPE.

Who is the main contact?  
Dr JG Meechan  
john.meechan@newcastle.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr John Meechan

**Contact details**  
Oral Surgery  
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United Kingdom  
NE2 4BW

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
A double-blind cross-over trial with healthy adult volunteers comparing molar buccal infiltrations to canine buccal infiltrations for anaesthesia of mandibular teeth

**Study objectives**  
Mandibular molar infiltrations with articaine have the same mode of action as deposition of local anaesthetic solution at the mental foramen, so therefore a modified mental and incisive nerve block.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee North East - Newcastle and North Tyneside 1, 18/07/2011, ref: 11/NE/0050

**Study design**

Double-blind placebo-controlled cross-over single-centre study

**Primary study design**

Interventional

**Secondary study design**

Randomised cross over trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Dental local anaesthesia

**Interventions**

1.8ml 4% articaine hydrochloride with 1:100000 adrenaline injected in the mucobuccal fold opposite either the lower 1st molar, 2nd molar or canine tooth.  
Placebo is needle penetration only.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Response to electronic pulp testing indicating pulpal anaesthesia

**Secondary outcome measures**

Injection discomfort using a Visual Analogue Scale

**Overall study start date**

06/02/2012

**Completion date**

31/07/2012

# Eligibility

## Key inclusion criteria

Volunteers that are aged 18-30 years, with vital molar, first and second premolar, canine and incisor teeth that are not restored.

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

30 Years

## Sex

Both

## Target number of participants

22

## Key exclusion criteria

1. Volunteers that are under 18 or over 30 years of age
2. Those unable to give consent
3. Those with self reported bleeding disorders, orofacial anaesthesia or paraesthesia, allergies to local anaesthetic drugs, pregnancy at time of study or with teeth that respond negatively to baseline pulp testing or key test teeth missing

## Date of first enrolment

06/02/2012

## Date of final enrolment

31/07/2012

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Newcastle University**  
Newcastle Upon Tyne  
United Kingdom  
NE2 4BW

## **Sponsor information**

### **Organisation**

Newcastle Hospitals NHS Foundation Trust (UK)

### **Sponsor details**

Joint Research Office  
Level 6, Leazes Wing  
Royal Victoria Infirmary  
Queen Victoria Road  
Newcastle Upon Tyne  
England  
United Kingdom  
NE1 4LP

### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.newcastle-hospitals.org.uk/>

### **ROR**

<https://ror.org/05p40t847>

## **Funder(s)**

### **Funder type**

Industry

### **Funder Name**

M ESPE (UK)

## **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	01/04/2013		Yes	No