

# Efficacy of incisive nerve block for pulp anaesthesia in the mandible

<b>Submission date</b> 26/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/08/2013	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

There is not much published evidence on the effectiveness of the incisive/mental nerve block (IMNB) for anaesthesia of lower premolar and incisor teeth. Anecdotal reports have suggested that soft tissue massage over the area of injection may help local anaesthetic to move into the lower jaw and improve the effectiveness of the injection. This has never been tested in a clinical trial.

The aim of this study was to assess the effect of soft tissue massage on the effectiveness and distribution of anaesthesia following IMNB. In addition, the speed of onset of anaesthesia and the discomfort associated with IMNB and soft tissue massage were investigated.

### Who can participate?

Healthy adults were recruited to the study.

### What does the study involve?

Participants attended on two occasions, at least 1 week apart, and received an IMNB injection on each occasion. One of the injections was followed by manual massage of the soft tissues over the place of injection, the other being followed by dummy massage on the adjacent teeth. The order of real or dummy massage was determined randomly. Participants were asked to report how much discomfort was associated with the injection and following massage. During the next 45 minutes, teeth were tested with an electronic pulp tester to assess whether their nerves had feeling.

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

Benefits include contributing to the body of knowledge on dental local anaesthesia and helping to improve the comfort and care of dental patients in the future. Risks include slight bruising and discomfort at the site of injection, accidental damage to lips and gums when they are numb and unexpected adverse reactions to local anaesthetic agents.

### Where is the study run from?

Newcastle Dental Hospital, Newcastle Hospitals NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?  
The study started in May 2008 and ran January 2009.

Who is funding the study?  
Newcastle University (UK).

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

**Type(s)**  
Scientific

**Contact name**  
Dr John Whitworth

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
4202 version 2

## Study information

**Scientific Title**

### Study objectives

This study will assess the effect of soft tissue massage on the efficacy and distribution of anaesthesia following incisive nerve block, using 2% lidocaine and 1:80,000 epinephrine. The null hypothesis is that massage of the injection site has no effect on the efficacy and distribution of pulp anaesthesia after incisive nerve block injection.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Northumberland Research Ethics Committee. Date of approval: 20/11/2007 (ref: 07/H0902/49)

**Study design**

Randomised, double-blind, cross-over trial.

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Not Specified

**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**

Anaesthesia in the mandible

**Interventions**

This is a randomised, double-blind, cross-over study. Each volunteer will receive 2 incisive nerve block injections in the mouth, one with and one without massage of the injection site, in random order over 2 visits (one injection per visit). All injections will be given by an experienced dentist. The digital massage of the injection site will be done after the injection for 60 seconds.

Incisive nerve block injection: 2% lidocaine + 1:80,000 epinephrine

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Lidocaine and epinephrine

**Primary outcome measure**

Numbness of lower teeth (back teeth) following local anaesthetic injection. This will be assessed by electric pulp testing every 2 minutes after injection for the first 10 minutes then every 5 minutes until 45 minutes.

**Secondary outcome measures**

1. Injection discomfort, assessed with a visual analogue scale at each visit
2. Duration of numbness after injection

**Overall study start date**

01/05/2008

**Completion date**

01/01/2009

**Eligibility****Key inclusion criteria**

1. Healthy adult volunteers
2. Staff or students at the Newcastle University

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

38 volunteers

**Key exclusion criteria**

The volunteers:

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

The teeth:

1. Teeth which respond negatively to baseline pulp testing
2. Key test teeth missing

**Date of first enrolment**

01/05/2008

**Date of final enrolment**

01/01/2009

**Locations**

**Countries of recruitment**

England

United Kingdom

**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)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

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

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Newcastle upon Tyne Hospitals NHS Foundation Trust (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	01/03/2013		Yes	No