

# Efficacy of Anterior Middle Superior Alveolar nerve block (AMSA) versus Infra Orbital Nerve Block (IONB) for dental pulp and soft tissue anaesthesia in the anterior maxilla

<b>Submission date</b> 18/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/11/2012	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English Summary

Background and study aims:

Teeth in the upper jaw are usually anaesthetised (made numb) for dental treatment by injecting local anaesthetic solution above the tooth to be worked upon. Although less commonly done in the upper jaw than the lower, multiple teeth can be anaesthetised by a single injection that blocks conduction in a more major nerve, such as the Infra-Orbital, Anterior or Middle Superior Alveolar Nerves. There are no previously published studies comparing the effectiveness of nerve blocks in the upper jaw.

The study was carried out to see whether the Anterior/Middle Superior Alveolar Nerve block (AMSA) and Infra-Orbital Nerve block (IONB) work as well, for as long, and as quickly as one another and that both injections are associated with similar levels of discomfort.

Who can participate?

Twenty eight healthy adults were recruited to the study. We were unable to accept: individuals under 18 years of age; those unable to give informed consent; individuals with medical conditions including bleeding disorders, disturbances of sensation, allergies to dental local anaesthetic drugs, pregnant women and those with missing or dead upper teeth.

What does the study involve?

Participants attended on two occasions, at least 1 week apart and received an AMSA injection on one of the appointments and an IONB injection on the other. The order was randomly allocated. Both injections were of lidocaine with adrenaline, administered by the same person, using a computer-controlled injection system. Participants were invited to rate any discomfort associated with the injections.

During the next 47 minutes, teeth were tested with an electronic pulp tester to assess whether their nerves had feeling.

Participants were asked to report back how long their lip had felt numb after the injection.

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 sites of injection, accidental damage to lips and gums when they are numb and unexpected bad reactions to local anaesthetic agents.

Where is the study run from?

Newcastle Dental Hospital, Newcastle Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?

The study was run in the spring of 2008, and lasted for approximately 1 month.

Who is funding the study?

Newcastle University

Who is the main contact?

Dr John Whitworth

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## Contact information

### Type(s)

Scientific

### Contact name

Dr John Whitworth

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LH- 4327

## Study information

Scientific Title

**Acronym**

AMSA vs IONB in anterior maxilla

**Study hypothesis**

1. Which of the two techniques under investigation most reliably makes upper front teeth numb?
2. How long does numbness last after each injection method?
3. Which injection technique is the most comfortable to receive?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved by the Newcastle & North Tyneside 1 Research Ethics Committee on the 13 December 2007 (ref: 07/H0906/140)

**Study design**

Randomized double-blind cross-over study.

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

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

**Condition**

Local anaesthetic techniques in anterior maxilla

**Interventions**

Each participant receives 3 different local anaesthetic injections in the mouth in random order (1 injection per visit, 3 visits in total).

Methods of local anaesthetic injections:

1. AMSA: 1 mL of 2% lidocaine with 1:80,000 epinephrine will be given as an AMSA, depositing solution in the palatal mucosa at a point that bisects the maxillary first and second premolars, mid-way between the crest of the gingival margin and the mid palatine suture
2. IONB: 1 mL of 2% lidocaine with 1:80,000 epinephrine will be given as an IONB, inserting the needle at the height of the mucobuccal fold between the first and second maxillary premolars and advancing to the manually-palpated infra-orbital foramen before depositing solution
3. IONB: 2 mL of 2% lidocaine with 1:80,000 epinephrine will be given as an IONB as above

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Numbness of upper front teeth following local anaesthetic injection, assessed by electric pulp testing at each visit (Average duration of procedure: 1 hour)

**Secondary outcome measures**

1. Injection discomfort, assessed by visual analogue scales after each visit
2. Duration of numbness after local anaesthetic injection, assessed by a questionnaire to record the duration of lip numbness after each visit/injection

**Overall study start date**

07/01/2008

**Overall study end date**

07/07/2009

**Eligibility****Participant inclusion criteria**

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

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

28 volunteers

**Participant 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

**Recruitment start date**

07/01/2008

**Recruitment end date**

07/07/2009

## **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

**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	01/12/2010		Yes	No