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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

Submission date
18/12/2007

Recruitment status
No longer recruiting

Registration date
22/02/2008

Overall study status
Completed

Last Edited
26/11/2012

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

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?
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Contact information

Type(s)
Scientific

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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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
07/07/2009

Eligibility

Key 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

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
07/01/2008

Date of final enrolment
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)

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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?
Results article	results	01/12/2010		Yes	No