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Efficacy of incisive nerve block for pulp anaesthesia in the mandible

Submission date	Recruitment status	[_] Prospectively registered
26/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/08/2013	Oral Health	

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
john.whitworth@newcastle.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr John Whitworth

Contact details
School of Dental Sciences
Newcastle University
Framlington Place
Newcastle upon Tyne
United Kingdom
NE2 4BW
+44 (0)1912 227825
J.M.Whitworth@ncl.ac.uk

Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Randomised, double-blind, cross-over trial.

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s)
1. Injection discomfort, assessed with a visual analogue scale at each visit
2. Duration of numbness after injection

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
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	01/03/2013		Yes	No