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How do dental injections make your lower teeth go numb?

Submission date 09/02/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/04/2012	**Overall study status** Completed	
Last Edited 20/08/2015	**Condition category** Oral Health	

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
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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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 articiane 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, preganancy 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?
Results article	results	01/04/2013		Yes	No