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Efficacy of articaine infiltration for pulp anaesthesia in adult mandibular teeth

Submission date	Recruitment status	[_] Prospectively registered
27/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2013	Oral Health	

Plain English summary of protocol

Background and study aims.
This study in healthy volunteers was designed to test different methods of numbing up teeth in the bottom jaw. Teeth in the bottom jaw are normally numbed up by placing an injection of a solution known as a local anaesthetic at the back of the mouth. This numbs all the teeth on that side of the lower jaw. This method is technique-sensitive and does not always provide numbness of all the teeth. This is often because the target site for the injection is not in the same place in every patient. Unfortunately the desired target is not visible to the naked eye and relies on landmarks that vary between individuals. In this study we were investigating a simpler method of numbing up lower teeth by injecting the local anaesthetic into the gum beside the tooth to be treated. This is a much simpler method than the traditional technique but is not often used as it has been shown to have poor success with the traditional local anaesthetics used in dentistry. We have shown in earlier investigations that the most recently introduced local anaesthetic in dentistry (a drug known as articaine) can be effective in the lower jaw when injected next to the tooth to be treated.
In this study we wanted to test a number of things. Firstly, we wanted to see if it mattered on which side of the tooth the gum was injected (the tongue side or the cheek side). Secondly, we wanted to see if teeth further away from the point of injection were also numbed up.

Who can participate?
Anyone over 18 years of age with sufficient sound teeth in the lower jaw and in good general health could participate.

What does the study involve?
We injected at three different points at different stages of the study. One point was into the gum on the cheek side next to a back tooth, we did a similar thing next to a front tooth. The third point of injection was into the gum on the tongue side of a back tooth. The effect of the injections was determined by testing the teeth by a machine that transmits little electrical impulses to the tooth. The patient cannot feel these impulses when the tooth is properly numb. We tested the numbness of a number of teeth in the lower jaw (close to and distant from the point of injection) for 45 minutes after the injection of the local anaesthetic.

What are the possible benefits and risks of participating?
There was no direct benefit from participating however the results were used to inform dental practice. Minor bleeding and a feeling of prolonged numbness were potential risks of participation.

Where is the study run from?
Newcastle University

When is the study starting and how long is it expected to run for?
The study started in March 2009 and ended in September 2009.

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Dr John Meechan
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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
4805 version 1

Study information

Scientific Title

Efficacy of articaine infiltration for pulp anaesthesia in adult mandibular teeth: a randomised double-blind cross-over study

Study objectives
1. To determine the efficacy of articaine buccal infiltration in the molar region alone for pulp anaesthesia in mandibular first and second molars, premolars and central and lateral incisors
2. To investigate the efficacy of articaine lingual infiltration in the molar region alone for pulp anaesthesia in the same teeth
3. To investigate the effect of bilateral articaine buccal infiltrations in the mandibular first molar regions on pulp anaesthesia in the same teeth
4. To investigate the spread of local anaesthetic solution posteriorly after articaine infiltration in the mandibular central incisor region

Ethics approval required
Old ethics approval format

Ethics approval(s)
A favourable ethical opinion was given for this study by Newcastle and North Tyneside 2 Research Ethics Committee on the 26th February 2009 (ref: 09/H0907/4)

Study design
Randomised 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
Pulp anaesthesia in adult mandibular teeth

Interventions
1. Local anaesthetics, average number per participant one injection per visit, average time taken five minutes. All injections will be given by an experienced dentist.
2. Electeric pulp testing: electronic pulp testing of the test teeth will be performed by an experienced dentist trained in the method, 73 per visit average time taken one hour
3. Other questionnaire which is completion of visual analogue scales (one each visit) to record injection discomfort. Average number per participant is four and average time taken is one minute.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Numbness of lower anterior and posterior teeth (front and back teeth) following local anaesthetic injection; measured from one minute after the injection of local anaesthetic solution until 47 minutes.

Secondary outcome measures
Injection discomfort (recorded immediately after injection) and duration of numbness after injection of anaesthetic solution (measured from one minutes after injection until 47 minutes).

Overall study start date
01/03/2009

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. Healthy adult volunteers (aged 18 years or older, either sex)
2. Staff or students at Newcastle University

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 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
01/03/2009

Date of final enrolment
01/09/2009

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

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?
Results article	results	01/07/2011		Yes	No