ISRCTN21993885 https://doi.org/10.1186/ISRCTN21993885

The efficacy of infiltration anaesthesia for adult mandibular incisor teeth

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
28/03/2012	Oral Health	

Plain English summary of protocol
Not provided at time of registration

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2812 version 1

Study information

Scientific Title

Study objectives
This study will compare the buccal injection alone and combination of buccal and lingual injections in lower front teeth using two local anaesthetic drugs which are routinely used in dentistry (lidocaine and articaine), both with epinephrine.

Study questions:
1. Which of the two methods under investigation most reliably makes lower 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)
Newcastle & North Tyneside 1 Research Ethics Committee. Date of approval: 29/06/2004. Substantial amendments approved on 27/05/2005 (ref: 04/Q0905/27)

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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 methods in anterior mandible

Interventions
This is a randomised, double-blind, cross-over study. Each volunteer will receive 4 local anaesthetic injections in random order in the mouth over 4 visits (one injection per visit). All injections will be given by an experienced dentist.

Injections:
1. 1.8 mL of 2% lidocaine with 1:100,000 epinephrine as a buccal injection
2. 0.9 mL of 2% lidocaine with 1:100,000 epinephrine for both buccal and lingual injections
3. 1.8 mL of 4% articaine with 1:100,000 epinephrine as a buccal injection
4. 0.9 mL of 4% articaine with 1:100,000 epinephrine for both buccal and lingual injections

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lidocaine, articaine and epinephrine.

Primary outcome measure
Numbness of lower anterior teeth (front teeth) following local anaesthetic injection. This will be assessed by electric pulp testing every 2 minutes after injection for 30 minutes then every 5 minutes until 45 minutes.

Secondary outcome measures
1. Injection discomfort, assessed by a visual analogue scale at each visit
2. Duration of numbness after injection
3. Spreading of anaesthetic solution to adjacent teeth

Overall study start date
29/10/2007

Completion date
29/10/2008

Eligibility

Key inclusion criteria
1. Healthy adult volunteers, both men and women
2. Staff or students at the Newcastle University

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
31

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
29/10/2007

Date of final enrolment
29/10/2008

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
c/o Ms Amanda Tortice
Research and Developments Office
Fourth floor
Leazes Wing
Royal Victoria Infirmary
Newcastle upon Tyne
England

United Kingdom
NE1 4LP
+44 (0)1912 825959
Amanda.Tortice@nuth.nhs.uk

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	01/11/2010		Yes	No