The efficacy of infiltration anaesthesia for adult mandibular incisor teeth

Submission date	Recruitment status No longer recruiting	Prospectively registered		
26/03/2008		☐ Protocol		
Registration date 09/05/2008	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 28/03/2012	Condition category Oral Health	[] Individual participant data		

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