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A comparative study of two digital anaesthetic techniques

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/10/2011	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Bruce Whiteley

Contact details
Senior Podiatrist
Therapy Centre
'O' Block, West Middlesex University Hospital
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0082164453

Study information

Scientific Title

Study objectives
Does the administration of local anaesthetic in two stages rather than one stage reduce the length of time the patient experience pain and/or the degree of pain?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Hounslow and Hillingdon Research Ethics Committee in May 2005 (ref: 05Q0407/32).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Nails

Interventions
Two different methods of local anaesthesia for nail surgery under local anaesthetic will be carried out on a population attending a therapy centre at a district hospital. Recruitment will be consecutive and patients will be randomly assigned a number which will indicate to the clinician which technique to administer to which side of the great toe. The decision to use method 1 or 2 will be random/alternated medially and laterally to eliminate any bias. The patient will not know which is the standard and which the variant technique. Therefore, the study is single blinded.

During the administration of local anaesthetic, patients will be given a stopwatch and asked to time the period they feel pain/discomfort. The watch is stopped when there is a cessation of pain. The watch will be stopped if running, when the needle is withdrawn from the toe at the end of delivery. In order to numb the patients toe, an injection must be given to either side of the toe. This is typically a very small amount of fluid per injection e.g. between 1 and 2 millilitres. We will inject one side of the toe using method 1 and the other side using method 2.

1. Method 1 involves giving the injection in one go
2. Method 2 involves giving the injection in two stages. A small amount is given initially and the needle is withdrawn. After waiting two minutes a further injection is given into the same site using the remainder of the cartridge.

During each injection, the patient will be given a stopwatch and asked to start it when they experience discomfort and stop the watch when this goes away. Some people may wish to start and stop the watch a number of times. After each injection the patient will be asked to indicate the level of pain on a 10 cm visual analogue scale and register their preferences for method 1, method 2, or neither.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
An assessment of which method of local anaesthesia is experienced as least painful by patients entered into the study: length of time pain is experienced and intensity of pain experienced for the two methods being compared.

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/12/2004

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Fifty patients will be recruited into the study. Each patient will act as his or her own control.
Inclusion criteria are:
1. Patient is suitable for digital local anaesthesia for nail surgery
2. Requires partial nail avulasion - medial, lateral or both.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patients who have mental health problems/learning disabilities
2. Needle phobia
3. Known psychosomatic reaction to injections
4. Being under 16 years old
5. Inability to use a stopwatch (to stop and start when pain is felt/stops being felt)
6. Patients who have peripheral neuropathy

Date of first enrolment
11/12/2004

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Senior Podiatrist
Isleworth
United Kingdom
TW7 6AF

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Hounslow Primary Care Trust (UK)

Funder Name
NHS R&D Support Funding (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	01/03/2010		Yes	No