

A comparative study of two digital anaesthetic techniques

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

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

Protocol serial number
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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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 The watch will be stopped if running, when the needle is withdrawn from the toe at the end of delivery.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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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 avulsion - medial, lateral or both.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Senior Podiatrist

Isleworth

United Kingdom

TW7 6AF

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

Hounslow Primary Care Trust (UK)

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

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