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A prospective study to assess the effectiveness of lignocaine versus normal saline in the reduction of pain associated with dressing removal in fingertip injuries

Submission date 28/09/2007	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 27/08/2008	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0077183569

Study information

Scientific Title

Study objectives
Does local anaesthetic (lignocaine) reduce pain associated with dressing removal of fingertip injuries when compared to normal saline?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
Patients will be recruited from the Pulvertaft Hand Center upon clinic appointment. This is a stop interview /evaluation that takes place in the Hand Clinic. Certain data will be collected - age, sex, nature of injury, etc. This will be kept confidential. Patients will be asked whether they would like to be involved in the study. Those patients who agree will be asked to sign a consent form. The patients who do not wish to participate in the study will receive the normal standard of care for such injuries, ie. normal saline.

The following protocol will be set up:
- Affected finger will be immersed in 10 milliliters of local anaesthetic (lignocaine) or normal

saline.
- The dressing is then removed by the sister in the clinic and the patient asked to log their level of pain. This will be achieved by a simple (linear analogue) scoring system.

The whole process will be randomised and blind to those involved in the study to avoid or prevent bias.

Added 27 August 2008: trial was stopped.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
lignocaine versus normal saline

Primary outcome measure
The reduction in the level of pain on dressing removal of patients with fingertip wounds as shown on the linear visual analogue pain scale, 0-10, 0 being the lowest level of pain and 10 the highest level of pain.

Secondary outcome measures
No secondary outcome measures

Overall study start date
21/08/2006

Completion date
31/01/2008

Reason abandoned (if study stopped)
Too much bureaucracy

Eligibility

Key inclusion criteria
1. Patients sustaining a nail bed injury
2. Patients who are old enough to give consent (over 16 years old)
3. Patients willing to participate

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
98

Key exclusion criteria
1. Patients who are unable to give consent
2. Previous injury or surgery to the presenting digit
3. Patients within any other concomitant trial involving analgesics, patient allergy to lignocaine

Date of first enrolment
21/08/2006

Date of final enrolment
31/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
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DE1 2QY

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
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dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

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