# Clinical trial results:
# A prospective study to assess the effectiveness of lignocaine versus normal saline in the reduction of pain associated with dressing removal in finger tip injuries

## Summary

| | |
|---|---|
| EudraCT number | 2005-005591-32 |
| Trial protocol | GB |
| Global end of trial date | 26 March 2008 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 04 January 2017 |
| First version publication date | 04 January 2017 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | RD-5103-036-05 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | DHRD/2006/029: R&D Reference |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Derby Teaching Hospitals NHS Foundation Trust |
| Sponsor organisation address | Uttoxeter Road, Derby, United Kingdom, DE22 3DT |
| Public contact | Teresa Grieve, Derby Teaching Hospitals NHS Foundation Trust, +44 1332724639, DHFT.sponsor@nhs.net |
| Scientific contact | Teresa Grieve, Derby Teaching Hospitals NHS Foundation Trust, +44 1332724639, DHFT.sponsor@nhs.net |

Notes:

### Paediatric regulatory details

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 05 August 2008 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 26 March 2008 |
| Global end of trial reached? | Yes |
| Global end of trial date | 26 March 2008 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To determine whether local anaesthetic (lignocaine) reduces pain associated with dressing removal of fingertip injuries when compared to normal saline

Protection of trial subjects:

Lignocaine 1% was routinely used at the Pulvertaft Hand Centre. The solution was used topically and only a minimal amount of solution came into contact with the participants skin, no solution was expected to be absorbed systemically. Patients were also questioned during the consent process to identify possible reactions to lignocaine. There was no potential for discomfort or pain over and above what would have been experienced by patients receiving standard hospital care of soaking in normal saline.

Background therapy: -

Evidence for comparator:

Soaking wound dressings in saline was standard practice within the Pulvertaft Hand Centre.

| | |
|---|---|
| Actual start date of recruitment | 01 September 2006 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | United Kingdom: 20 |
| Worldwide total number of subjects | 20 |
| EEA total number of subjects | 20 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 1 |
| Adults (18-64 years) | 17 |
| From 65 to 84 years | 2 |

| | |
|---|---|
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Participants were recruited from patients attending the Pulvertaft Hand Centre with fingertip injuries upon clinic appointment between 1st September 2006 and 5th November 2007.

### Pre-assignment

Screening details:

Any patient with a fingertip injury was approached by the Lead Sister at the Pulvertaft Hand Centre. Patients were given a patient information leaflet describing the study and were free to ask questions.

### Period 1

| | |
|---|---|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Investigator, Subject |

Blinding implementation details:

Both lignocaine and 0.9% saline were stored within a locked cupboard in their original packaging and in a separate box to clinic drugs. Out of sight of the researcher and the patient, the solution used was selected and put into a galipot by a member of staff other than the researcher. The identity of the solution was unknown to all research members and trial participants.

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Lignocaine 1% |

Arm description:

Wound dressing removal with 1% Lignocaine. The affected digit (with all outer dressings removed) will be immersed into a galipot containing 10ml of 1% lignocaine for a period of ten minutes. The volume of fluid used was increased to 20ml following submission of a substantial amendment in March 2007 as 10ml was insufficient to reach the skin surface due to bulky dressing's. The dressing was then removed by a nurse in the clinic and the patient logged their level on pain on a linear visual analogue pain score.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | 1% w/v Lidocaine Injection BP |
| Investigational medicinal product code | |
| Other name | Lignocaine |
| Pharmaceutical forms | Injection |
| Routes of administration | Topical use |

Dosage and administration details:

The affected digit was soaked in 10ml of 1% lignocaine for 10 minutes. The volume of fluid was increased to 20ml following submission of a substantial amendment in March 2007, as 10ml was insufficient to reach the skin surface with bulky dressings.

| | |
|---|---|
| **Arm title** | Saline 0.9% |

Arm description:

Wound dressing removal with 0.9% Saline. The affected digit (with all outer dressings removed) will be immersed into a galipot containing 10ml of 0.9% Saline for a period of ten minutes. The volume of fluid used was increased to 20ml following submission of a substantial amendment in March 2007 as 10ml was insufficient to reach the skin surface due to bulky dressing's. The dressing was then removed by a nurse in the clinic and the patient logged their level on pain on a linear visual analogue pain score

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Sodium Chloride 0.9% w/v Injection BP |
| Investigational medicinal product code | |
| Other name | Saline |
| Pharmaceutical forms | Injection |
| Routes of administration | Topical use |

Dosage and administration details:

The affected digit was soaked in 10ml of 0.9% saline for a period of 10 minutes. The volume of fluid was increased to 20ml following submission of a substantial amendment in March 2007, as 10ml was insufficient to reach the skin surface with bulky dressings.

| **Number of subjects in period 1** | Lignocaine 1% | Saline 0.9% |
|---|---|---|
| Started | 8 | 12 |
| Completed | 8 | 12 |

## Baseline characteristics

### Reporting groups

| Reporting group title | Lignocaine 1% |
|---|---|

Reporting group description:

Wound dressing removal with 1% Lignocaine. The affected digit (with all outer dressings removed) will be immersed into a galipot containing 10ml of 1% lignocaine for a period of ten minutes. The volume of fluid used was increased to 20ml following submission of a substantial amendment in March 2007 as 10ml was insufficient to reach the skin surface due to bulky dressing's. The dressing was then removed by a nurse in the clinic and the patient logged their level on pain on a linear visual analogue pain score.

| Reporting group title | Saline 0.9% |
|---|---|

Reporting group description:

Wound dressing removal with 0.9% Saline. The affected digit (with all outer dressings removed) will be immersed into a galipot containing 10ml of 0.9% Saline for a period of ten minutes. The volume of fluid used was increased to 20ml following submission of a substantial amendment in March 2007 as 10ml was insufficient to reach the skin surface due to bulky dressing's. The dressing was then removed by a nurse in the clinic and the patient logged their level on pain on a linear visual analogue pain score

| Reporting group values | Lignocaine 1% | Saline 0.9% | Total |
|---|---|---|---|
| Number of subjects | 8 | 12 | 20 |
| Age categorical | | | |
| Statistical analysis at baseline was not performed by age | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Not recorded | 8 | 12 | 20 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 0 | 0 | 0 |
| Male | 0 | 0 | 0 |
| Not recorded | 8 | 12 | 20 |

### Subject analysis sets

| Subject analysis set title | Final analysis |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Subjects with complete Visual Analogue Scores were included in the analysis.

| **Reporting group values** | Final analysis | | |
|---|---|---|---|
| Number of subjects | 20 | | |
| Age categorical | | | |
| Statistical analysis at baseline was not performed by age | | | |
| Units: Subjects | | | |
| In utero | 0 | | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | | |
| Newborns (0-27 days) | 0 | | |
| Infants and toddlers (28 days-23 months) | 0 | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 0 | | |
| From 65-84 years | 0 | | |
| 85 years and over | 0 | | |
| Not recorded | 20 | | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 0 | | |
| Male | 0 | | |
| Not recorded | 20 | | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Lignocaine 1% |

Reporting group description:

Wound dressing removal with 1% Lignocaine. The affected digit (with all outer dressings removed) will be immersed into a galipot containing 10ml of 1% lignocaine for a period of ten minutes. The volume of fluid used was increased to 20ml following submission of a substantial amendment in March 2007 as 10ml was insufficient to reach the skin surface due to bulky dressing's. The dressing was then removed by a nurse in the clinic and the patient logged their level on pain on a linear visual analogue pain score.

| | |
|---|---|
| Reporting group title | Saline 0.9% |

Reporting group description:

Wound dressing removal with 0.9% Saline. The affected digit (with all outer dressings removed) will be immersed into a galipot containing 10ml of 0.9% Saline for a period of ten minutes. The volume of fluid used was increased to 20ml following submission of a substantial amendment in March 2007 as 10ml was insufficient to reach the skin surface due to bulky dressing's. The dressing was then removed by a nurse in the clinic and the patient logged their level on pain on a linear visual analogue pain score

| | |
|---|---|
| Subject analysis set title | Final analysis |
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Subjects with complete Visual Analogue Scores were included in the analysis.

### Primary: VAS pain

| | |
|---|---|
| End point title | VAS pain |

End point description:

| | |
|---|---|
| End point type | Primary |

End point timeframe:

At Baseline

| **End point values** | Lignocaine 1% | Saline 0.9% | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 8 | 12 | | |
| Units: cm | | | | |
| median (inter-quartile range (Q1-Q3)) | 2.3 (0.25 to 2.55) | 1.6 (0.55 to 5.35) | | |

### Statistical analyses

| **Statistical analysis title** | Mann U Whittney |
|---|---|
| Comparison groups | Lignocaine 1% v Saline 0.9% |

| | |
|---|---|
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.615 |
| Method | Wilcoxon (Mann-Whitney) |

## Adverse events

### Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events were collected throughout trial participation (length of trial participation is 1 visit of approximately 10-20 minutes)

| | |
|---|---|
| Assessment type | Non-systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | N/A |
| Dictionary version | 0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Overall trial |

Reporting group description:

This group describes all participants within the trial (participants from the 1% Lignocaine arm, and participants from the 0.9% saline arm)

| **Serious adverse events** | Overall trial | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 20 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

Frequency threshold for reporting non-serious adverse events: 5 %

| **Non-serious adverse events** | Overall trial | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 20 (0.00%) | | |

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Adverse events were collected for the full duration that participants were on the trial however this was only for the duration of the clinic visit, there was no patient follow up. As such no adverse events occurred.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 14 March 2007 | The volume of fluid used was increased from 10ml to 20ml to accomodate bulky dressings. 10ml was insufficient to reach the skin surface, the increase in volume will ensure that the fluid reaches the skins surface regardless of the type of dressing used. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The trial did not reach its recruitment target due to standard clinic pressures, the time taken for a research appointment over that of standard care appointment in a busy clinic resulted in slow and problematic recruitment.

Notes: