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 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: