



Clinical trial results:

A dose finding study for ultrasound guided anterior psoas compartment blocks in patients with a fractured neck of femur

Summary

EudraCT number	2009-013462-25
Trial protocol	GB
Global end of trial date	04 April 2011

Results information

Result version number	v1 (current)
This version publication date	04 April 2019
First version publication date	04 April 2019

Trial information

Trial identification

Sponsor protocol code	GN09AN334
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00926666
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	NHS Greater Glasgow and Clyde Health Board
Sponsor organisation address	Dalnair Street, Glasgow, United Kingdom, G3 8SJ
Public contact	Dr Malcolm Watson, NHS Greater Glasgow and Clyde, 0044 141 452 3430, Malcolm.Watson@ggc.scot.nhs.uk
Scientific contact	Dr Malcolm Watson, NHS Greater Glasgow and Clyde, 0044 141 452 3430, Malcolm.Watson@ggc.scot.nhs.uk

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	04 April 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 April 2011
Global end of trial reached?	Yes
Global end of trial date	04 April 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Can we reduce the dose of local anaesthetic required to provide pain relief to patients with a broken hip by determining the dose based on the amount of the drug required to relieve pain?

Protection of trial subjects:

All patient recruited to this study received standard analgesia and anaesthesia for a emergency hip arthroplasty or fixation.

The only variable was the concentration of local anaesthetic used to provide an anterior psoas compartment block.

All peripheral nerve blocks have an associated risk. The commonest complication was peripheral neuropathy and the vast majority of these neuropathies were not present after 6 months.

The sighting of an anterior psoas compartment block (femoral nerve block) is considered to have an acceptable risk benefit ratio for elective and emergency hip and knee arthroplasty in current clinical practice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2010
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	0

Adults (18-64 years)	0
From 65 to 84 years	40
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

40 patients recruited from 1st Feb 2010 to 17th Nov 2010

Patients with a traumatic proximal femoral fracture scheduled for surgical hip fixation were recruited.

Pre-assignment

Screening details:

Potential recruits to the study were identified by the nursing and medical staff of the orthopaedic trauma ward.

Period 1

Period 1 title	Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Arm A and B
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Arm description:

Part A - A single 30ml dose of levobupivacaine with the dose concentration increased following an unsuccessful anterior psoas compartment block and decreased following an effective anterior psoas compartment block.

Part B - To estimate the duration of analgesia provided by the EC95 concentration of levobupivacaine estimated to provide ≥ 10 hours of analgesia from part A of this clinical trial and to determine if the peak plasma levobupivacaine concentrations are within safe limits.

Arm type	Experimental
Investigational medicinal product name	levobupivacaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Perineural use

Dosage and administration details:

Part A - The first 16 patients were treated with a starting concentration of 0.1% and the concentration was decreased or increased by 0.025% depending on whether the previous dose was effective or not. In part B the dose will be the same for all patients (calculated from the results of part A).

Number of subjects in period 1	Arm A and B
Started	40
Completed	36
Not completed	4
Physician decision	4

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm A and B
Reporting group description: Part A - A single 30ml dose of levobupivacaine with the dose concentration increased following an unsuccessful anterior psoas compartment block and decreased following an effective anterior psoas compartment block. Part B - To estimate the duration of analgesia provided by the EC95 concentration of levobupivacaine estimated to provide ≥ 10 hours of analgesia from part A of this clinical trial and to determine if the peak plasma levobupivacaine concentrations are within safe limits.	

Primary: Part A - Primary Outcome

End point title	Part A - Primary Outcome ^[1]
End point description: EC50 and EC95 concentrations of 30mls of levobupivacaine for ≥ 10 hours of analgesia after a femoral 3-in-1 nerve block.	
End point type	Primary
End point timeframe: From 3 in 1 nerve block administration to 24 hours post	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Details of the statistical analysis performed are within CIs PhD published. Results uploader not involved in study at all.	

End point values	Arm A and B			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: EC50 and EC95				
number (not applicable)	36			

Attachments (see zip file)	Part A Primary Endpoint/Part A primary end point table.docx
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Statistical analyses

No statistical analyses for this end point

Primary: Part B - Primary Outcome

End point title	Part B - Primary Outcome ^[2]
End point description: To estimate the duration of analgesia provided by the EC95 concentration of levobupivacaine estimated (using probit logistic regression analysis) to provide ≥ 10 hours of analgesia from part A of this clinical trial and to determine if the peak plasma levobupivacaine concentrations are within safe limits.	
End point type	Primary
End point timeframe: Nerve block administration to 24 hours	

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Details of the statistical analysis performed are within CIs PhD published.

Results uploader not involved in study at all.

End point values	Arm A and B			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Pain Score				
number (not applicable)	14			

Attachments (see zip file)	Part B - Primary Endpoint/Part B - Primary endpoint table.docx
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

A - From discharge from theatre, events were only reported and recorded if they are causally related to the anterior psoas compartment nerve block.

B - Adverse events occurring after the final pain scores are recorded (up to 24 hours later).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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Reporting groups

Reporting group title	Serious Adverse Events
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Reporting group description: -

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: These were not collected

Serious adverse events	Serious Adverse Events		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 40 (5.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Death from Breast cancer and comorbidities			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory, thoracic and mediastinal disorders			
Pulmonary tuberculosis			
subjects affected / exposed	1 / 40 (2.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Serious Adverse Events		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 40 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 August 2010	<ol style="list-style-type: none">1 prolongation of the maximum storage period of the IMP between preparation (by the pharmacy production unit) and patient administration,2 the insertion of a catheter after injection of the IMP to allow continued pain relief,3 a broadening of the inclusion criteria to include patients with proximal femoral fractures who will be managed non-surgically and patients with fractures of the femur around hip implants,4 a reduction in the IMP minimum dose to allow accurate estimation of the minimum effective concentration of levobupivacaine in 50% of patients.5 an improvement in the layout of the CRF form,6 a change in the way data from the trial will be analysed, which will not affect the primary end point,7 storage of the CRF (change of site due to building work),8 details on the biochemical analysis of the blood samples taken in the second part of the study to determine the levels of drug in the blood.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported