Final Report

Comparison of fascia iliac compartment block with conventional sedation to facilitate the positioning of patients with fractured neck of femur for spinal anaesthesia and the effect of nerve blockade on postoperative pain and mobility.

Sponsor Reference:	RGHT 000559 (BHSCT)
MHRA Reference :	2008-001568-35
Ethics Committee Reference:	08/NIR01/20

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The above study was commenced after approval by the Belfast Health & Social Care Trust R&D Committee, the Northern Ireland Research Ethics Committee and the Medicines and Healthcare Products Regulatory Committee.

This study was performed in two parts, as per the protocol.
In the initial part of the study, 40 patients undergoing operative repair of fractured neck of femur were randomised to receive either sedation or a fascia iliaca compartment block before positioning for spinal anaesthesia.

In the second part of the study, 60 patients with fractured neck of femur were randomised to receive a fascia iliaca compartment block with either lignocaine or levobupivacaine. Patients were then administered bolus dose levobupivaciane in the postoperative period and patient outcomes including pain scores, ability to mobilise and analgesia requirements were recorded.

There were no incidences of serious adverse events or SUSARs during the study period in any of the 100 patients recruited.

This study has been monitored by both the Clinical Research Support Sentre (Belfast Health & Social Care Trust) and the MHRA.

The results from the first part of this study have been accepted for presentation at the European Society of Anaesthesiologists conference in Helsinki (June 2010) and the abstract will be published in the European Journal of Anaesthesiology. Data from the remained of the study will be presented at a later date.

The data collected from this study is currently archived in the Department of Anaesthetics, Queens University Belfast. We are currently in discussion with the BHSCT regarding transfer of these documents to a Trust archive site.

ON COMPLETION OF YOUR PROJECT YOU MUST PROVIDE THE ROYAL RESEARCH OFFICE WITH A COMPLETION REPORT. *(THE REQUIRED CONTENTS OF WHICH ARE DETAILED BELOW)*	
Summary of findings *(Less than 150 words)*	☑
Summary of Serious Adverse Events	☑
Summary of SUSAR's	☑
Number of patients recruited/ withdrawn	☑
Final Financial report for the project (Total income - commercial projects only)	N/A
Details of dissemination of study findings (Publications, presentations, others)	☑
Details of where project info is to be archived	☑
Copy of final reports sent to ethics, MHRA or other external organisations	☑

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10th April 2010