

Final Report

Comparison of fascia iliaca compartment block or femoral nerve block using levobupivacaine for postoperative analgesia after operative repair of femoral neck fracture: a dose response study.

Sponsor Reference:	RGHT 000675 (BHSCT) <i>c/s</i>
MHRA Reference :	2009-013134-24
Ethics Committee Reference:	09/NIR02/39
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Research Fellow:	Dr RMG Hogg Department of Anaesthetics & ICM Belfast Health & Social Care Trust

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.

60 patients out of a planned 120 were recruited to this double blind, randomised controlled trial. A decision was made to stop the trial early due to a slower rate of recruitment than originally hoped for in the planned time frame. There was no safety or other reason for stopping this trial before the planned number of patients was recruited.

The trial aimed to compare the use of ultrasound guided fascia iliaca compartment blockade and femoral nerve blockade at two different doses for analgesia in patients undergoing operative repair of fractured neck of femur. The study demonstrated that at a lower dosage, fascia iliaca compartment blockade did not provide as good analgesia for positioning for spinal anaesthesia as the

other groups. The four groups were comparable for provision of postoperative analgesia with an overall low incidence of side effects.

There were no incidences of serious adverse events or SUSARs during the study period in any of the 60 patients recruited. This study has undergone regular auditing by the Clinical Research Support Centre (Belfast Health & Social Care Trust).

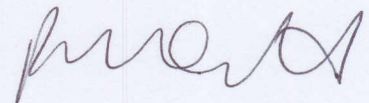
The results from this study have been included as part of a thesis towards the degree of Doctor of Medicine and submitted to Queens University Belfast. It is planned to publish this data at a later date in a peer-reviewed journal. The effect of the reduced numbers of patient recruitment on the power of the study has been taken into consideration.

The data collected from this study will be archived in a secure location in the Department of Anaesthetics, Belfast Health & Social Care Trust.

Dr Rosemary MG Hogg

Research Fellow

14th June 2011

A handwritten signature in dark ink, appearing to read 'R. Hogg', is written over the printed name and date.