

# Final Report

## Time to resumption of spontaneous respiration in patients administered either suxamethonium or rocuronium followed by sugammadex

<b>Sponsor Reference:</b>	09005RM-CS RVH (BHSCT)
<b>MHRA Reference :</b>	2009-010840-33
<b>Ethics Committee Reference:</b>	09/MRE00/66
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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.

Ninety adult patients undergoing orthopaedic surgery were included in the study and informed consent was obtained for all patients.

Patients were anaesthetised and randomised to receive either 1 mg kg<sup>-1</sup> of succinylcholine (n=30) or 1 mg kg<sup>-1</sup> of rocuronium (n=60). Three minutes after the muscle relaxant, 30 patients each in the Rocuronium group received 10 or 16 mg kg<sup>-1</sup> of Sugammadex and those in the Suxamethonium group 7-10 ml of normal saline.

The main endpoints recorded were the time to resumption of spontaneous ventilation as indicated by the return of diaphragmatic movement, movement of the reservoir bag, and recordable end-tidal CO<sub>2</sub>.

There was no significant difference in times to all clinical indices of recovery between any of the three groups. The number of patients whose SpO<sub>2</sub> decreased to less than 90% before start of breathing was 1, 3 and 4 in Rocuronium +



Sugammadex 16, Rocuronium + Sugammadex 10 and Suxamethonium groups respectively. The lowest SpO<sub>2</sub> values were not significantly different among the groups but the lowest SpO<sub>2</sub> was recorded in a patient receiving suxamethonium. Our results indicate that rocuronium can safely be used in place of succinylcholine as sugammadex 16 mg kg<sup>-1</sup> can restore spontaneous respiration in case of failure to intubate or ventilate with better safety than suxamethonium.

There were no incidences of serious adverse events or SUSARs during the study period in any of the 90 patients recruited.

This study has been monitored by the Clinical Research Support Centre (Belfast Health & Social Care Trust).

The results from this study will be presented at the Anaesthetic Research Society annual meeting in Nottingham (July 2010) with the abstract then published in the British Journal of Anaesthesia.

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.

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

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10<sup>th</sup> April 2010

