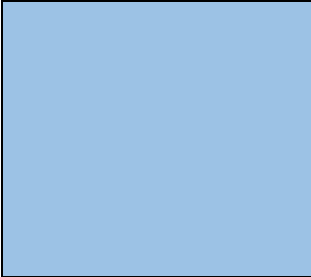


<b>STUDY TITLE</b>	<b>SPICE III RCT – Sedation Practice in Intensive Care Evaluation</b>
<b>STUDY POPULATION</b>	<b>Patient intubated and is receiving mechanical ventilation (unlikely to be extubated within 48 hours)</b>
<b>PRINCIPAL INVESTIGATOR</b>	Dato' Dr. Suhaini Kadiman
<b>STUDY COORDINATOR</b>	Izzatun Nafsi Sabran Contact number 03 – 2617 8200 ext 3122
<b>START DATE</b>	Oct 2013
<b>END DATE</b>	Till target achieved – 2000 subjects
<b>INCLUSION</b>	<ul style="list-style-type: none"> <li>• Subject has been intubated and is receiving mechanical ventilation</li> <li>• The treating clinicians expects that the patient will remain intubated until the day after tomorrow (unlikely to be extubated the following day)</li> <li>• The patient requiring immediate ongoing sedative medication for discomfort, safety, and to facilitate the delivery of life support measures</li> </ul>
<b>EXCLUSION</b>	<ul style="list-style-type: none"> <li>• Age less than 18 years</li> <li>• Patient is pregnant and/or lactating</li> <li>• Has been intubated (excluding time spent intubated within an operating theatre or transport) for <b>greater than 12 hours</b> in an intensive care unit</li> <li>• Proven or suspected acute primary brain lesion such as traumatic brain injury, intracranial haemorrhage, stroke, or hypoxic brain injury</li> <li>• Proven or suspected spinal cord injury or other pathology that may result in permanent or prolonged weakness</li> <li>• Admission as a consequence of a suspected or proven drug overdose or burns.</li> <li>• Administration of <b>ongoing</b> neuromuscular blockade</li> <li>• Mean arterial blood (MAP) pressure that is less than 50 mmHg despite adequate resuscitation and vasopressor therapy at time of randomization</li> <li>• Heart rate less than 55 beats per minute unless the patient is being treated with a betablocker or a high grade atrio-ventricular block in the absence of a functioning pacemaker</li> <li>• Known sensitivity to any of the study medications or the constituents of propofol (egg, soya or peanut protein)</li> <li>• Acute fulminant hepatic failure</li> </ul>

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- Patient has been receiving full time residential nursing care
  - Death is deemed to be imminent or inevitable during this admission and either the attending physician, patient or substitute decision maker is not committed to active treatment
  - Patient has an underlying disease that makes survival to 90 days unlikely
  - Patient has been previously enrolled in the SPICE study