Standard operating procedure

Protocol deviation

SOP No.4 | Version 1.1

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1. Purpose

This document describes the procedures for reporting a protocol deviation. This tells us about the practical challenges of using CPAP and how easily the findings of the PRISM trial can be implemented.

2. Protocol deviations

2.1 The following are pre-defined protocol deviations.

2.2 A participant in the intervention group who does not receive CPAP. This includes patients that unexpectedly remain intubated after surgery or where CPAP is started more than twelve hours after the end of surgery.

2.3 A participant in the usual care group who does receive CPAP. If this occurs within 12 hours of the end of surgery, investigators should consider this a protocol deviation.

2.4 Starting CPAP at a dose other than 5cmH_2O

2.5 Administration of CPAP for less than 4 hours duration for a patient in the intervention group.

2.6 Administration of CPAP with significant interruption for a patient in the intervention group. Brief interruptions to CPAP to adjust mask, for oral care or routine nursing care are considered part of the intervention. However, if the interruption is prolonged this should be considered a protocol deviation. Investigators will make a judgement about whether the interruption is prolonged and encouraged to record the duration of any interruption on a protocol deviation form. As a guide, a continuous

interruption of more than 15 minutes would usually be considered relevant.

2.7 Any other deviation from the specified protocol. This includes using different CPAP settings to those defined in the protocol.

3. Recording a protocol deviation

3.1 Protocol deviations should be recorded on the paper case report form and then entered on to the online database.

3.2 If, in response to an adverse event, CPAP is modified in a way that deviates from the protocol, then a protocol deviation should be recorded in addition to the adverse event.