Standard operating procedure

Adverse Event Reporting

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Authors: T. Abbott, R. Pearse

Authorisation: R. Pearse (chief investigator)

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1. Purpose

1.1 This document describes the procedures for reporting adverse events associated with the trial intervention, Continuous Positive Airway Pressure (CPAP).

1.2 CPAP is a very safe treatment that has been routinely used for over 30 years. Unexpected side effects directly related to, or caused by CPAP are therefore extremely unlikely to occur. However, in order to robustly ensure the safety of trial participants, the trial includes procedures for reporting adverse events to the trial management group.

2. Adverse events

2.1 An adverse event (AE) is an untoward medical occurrence in a PRISM trial participant. Generally, this may be any unfavourable and unintended sign, symptom or disease. However, because the safety of CPAP is well understood the reporting process is more defined than for other trials.

2.2 It is expected that patients undergoing major abdominal surgery may often suffer medical complications, up to and including death. It follows that a large number of PRISM trial participants will experience complications of surgery, which are completely unrelated to the trial intervention. In the PRISM trial, only AEs **clearly related to the use of CPAP** will be reported and it is anticipated that almost all of these will fall under one of the predefined categories within the CRF (see below).

2.3 The Principal Investigator (or suitably qualified nominee) is responsible for confirming the relatedness of any AE to the trial intervention.

2.4 The following list defines the AEs that are expected to occur as a result of CPAP. Where these occur, **and are deemed related to the use of CPAP**, they should be reported as an adverse event through the online PRISM CRF:

- Interface intolerance due to excessive air leaks
- Pain
- Cutaneous pressure sore or pressure area
- Claustrophobia
- Oro-nasal dryness
- Hypercapnia
- Haemodynamic instability
- Vomiting
- Aspiration of gastric contents into lungs

2.5 Some adverse events will not fit into the predefined categories listed above. In this case, please record as 'other' on the online PRISM CRF and provide a brief description of the adverse event. These must still be deemed to be related to CPAP use.

2.6 If an adverse event occurs, the clinician responsible for the patient should decide whether it is safe to continue CPAP, with or without modification, or whether CPAP should be discontinued.

3. Serious adverse events

3.1 Whilst unlikely, it is recognised that an AE related to CPAP may become a serious adverse event (SAE). Prompt reporting of SAEs is required to ensure any factors which affect the safety of other trial participants can be identified and acted upon. In the PRISM trial, an SAE must be assessed by the principal investigator (or suitably qualified nominee) as

probably or definitely caused by CPAP and meet at least one of the following criteria:

a) Results in death
b) Is life threatening
c) Clearly prolongs hospital stay
d) Causes significant disability or incapacity

3.2 Potential SAEs should be reported to the PRISM trial co-ordinating centre by email within 24 hours. The chief investigator will then determine whether an adverse event meets the criteria for an SAE, and consider what further action should be taken if any, to protect current and future trial participants. This may involve discussion with the principal investigator concerned, and if necessary, the independent chairs of the steering and data monitoring committees.

3.3 Confirmed SAEs will be reported by the trial management group to the sponsor and/or ethics committee as required by national research regulations for the country in question.

4 Recording and reporting of adverse events

4.1 Individual sites will record all adverse events (both AEs and potential SAEs) by completing the case report form supplementary document 'adverse events during CPAP'. This information should be submitted through the online database and paper copies should be kept locally.

4.2 Potential SAEs should be reported within 24 hours. Details of the SAE should be entered into the supplementary form 'adverse events during CPAP' section of the online PRISM CRF. In addition, an email should be sent to admin@prismtrial.org to notify the PRISM trial co-ordinating centre that a potential SAE has occurred. Please include the participant's trial number as identification. However, please do not send by email any patient identifiable data (name, date of birth, address etc),

other than the trial number. Specific details of the SAE will be taken from the online case report form.

4.3 Additional information may be requested by the PRISM trial co-ordinating centre, which should be provided within a timely manner.

5 Adverse event reporting decision tree