Standard operating procedure

Continuous Positive Airway Pressure (CPAP)

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1. Purpose

This document describes the procedures for the delivery of CPAP as part of the PRISM trial. The local principal investigator is responsible for ensuring that the provision of CPAP is consistent with this SOP.

2. Trial intervention

The trial intervention is defined as CPAP for at least four hours, with minimal interruption (e.g. for mouth care etc.), ideally started within four hours after the end of surgery. Where the start of CPAP has been delayed by exceptional circumstances (e.g. equipment failure, critical care admission, etc.), the intervention may be commenced up to twelve hours after the end of surgery.

3. Environment

3.1 CPAP should be delivered in an appropriate clinical environment, to be determined by the local principal investigator. The clinical area should have adequate staffing and equipment to safely monitor patients receiving CPAP as defined by local hospital policy.

3.2 Administration of CPAP will only take place under the direct supervision of appropriately trained staff.

3.3 Researchers may assist clinical staff to deliver CPAP at the discretion of the local principal investigator. However, ultimate responsibility for the

clinical care of the participant will remain with the clinical team at all times.

4. Equipment

4.1 Investigators may only use CPAP equipment approved for routine use in their hospital to deliver the intervention.

4.2 CPAP can be delivered using a facemask, nasal mask or helmet device according to participant or clinician preference.

4.3 The CPAP equipment should be cleaned and maintained at all times, in accordance with manufacturers' instructions and local hospital policy.

5. CPAP delivery

5.1 CPAP will ideally be started within four hours after the end of surgery. Where the start of CPAP has been delayed by exceptional circumstances (e.g. equipment failure, critical care admission, etc.), the intervention may be commenced up to twelve hours after the end of surgery.

5.2 The starting airway pressure will be 5 cmH_2O.

5.3 The airway pressure may be changed at the discretion of the responsible physician. The maximum permissible airway pressure during the trial intervention period will be 10 cmH_2O.

5.4 It may be beneficial to increase airway pressure above 5cm H_2O for patients with obesity or other cause of low chest wall compliance.

5.5 The minimum duration of CPAP will be four hours.

5.6 CPAP may be continued after the four-hour trial intervention period has finished, at the discretion of the responsible physician. All guidance on CPAP administration will then revert to the policy of the local hospital.

5.7 High flow nasal oxygen is not considered to be CPAP. The purpose of CPAP in the PRISM trial is to reverse pulmonary atelectasis and collapse, thus preventing respiratory failure. High flow nasal oxygen is a

treatment for hypoxia and is therefore not an equivalent form of respiratory support.

5.8 Short breaks in the delivery of CPAP during the intervention period for patient comfort (e.g. mouth care) are permissible and not considered a protocol deviation.

5.9 The use of nasogastric tubes during the delivery of CPAP is permissible at the discretion of the responsible clinician. The main advantage is to decompress the stomach in patients prone to swallowing air. However, a nasogastric tube can reduce the effectiveness of the CPAP seal. This should be considered carefully.

5.10 CPAP may be ineffective or contraindicated in patients with reduced level of consciousness.

6. Monitoring during CPAP

6.1 Participants receiving CPAP should be monitored according to local hospital policy on the delivery of CPAP.

6.2 Good practice includes monitoring of airway pressure and FiO_2.

7. Protocol deviation

7.1 The following should be recorded as protocol deviations:

a) Failure to administer CPAP to patients in the intervention group. This includes patients that unexpectedly remain intubated after surgery, or where CPAP is started more than twelve hours after the end of surgery

b) 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.

c) Starting CPAP at a dose other than $5cmH_2O$

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

e) 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.

f) Any other deviation from the specified protocol.

8. Intervention algorithm