

SECTION 4: TRIAL INTERVENTION PERIOD


SUBJECT #	_ _ _ - _ _ _ _	SITE #	_ _ _ _ _ _ _ _ _ _ _ _ _
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CPAP AFTER SURGERY		YES	NO
Did the patient receive Continuous Positive Airway Pressure (CPAP) started within twelve hours after the end of surgery?		<input type="checkbox"/>	<input type="checkbox"/>
If YES, please answer the following questions. If NO, please skip to next section.			
Date and time patient started CPAP	_ _ _ / _ _ _ _ / _ _ _ _ _ (DD/MMM/YYYY)	_ _ : _ _ (HR:MINS)	
Total duration of CPAP within twelve hours of the end of surgery		_ _ _ (MINS)	
Maximum airway pressure received during this period		_ _ _ cmH ₂ O	
Primary method of CPAP delivery (single most appropriate)			
Face mask		<input type="checkbox"/>	
Helmet device		<input type="checkbox"/>	
Nasal mask		<input type="checkbox"/>	
		YES	NO
Were extra research staff present to help deliver CPAP?		<input type="checkbox"/>	<input type="checkbox"/>
Did the staff administering CPAP use equipment to monitor airway pressures?		<input type="checkbox"/>	<input type="checkbox"/>
Did the staff administering CPAP use equipment to monitor the FiO ₂ ?		<input type="checkbox"/>	<input type="checkbox"/>
Did the patient have a nasogastric tube <i>in situ</i> during CPAP?		<input type="checkbox"/>	<input type="checkbox"/>

RESPIRATORY SUPPORT AFTER SURGERY		YES	NO
Did the patient receive any of the following within four hours of the end of surgery?			
Invasive mechanical ventilation		<input type="checkbox"/>	<input type="checkbox"/>
Non-invasive mechanical ventilation		<input type="checkbox"/>	<input type="checkbox"/>
High flow nasal oxygen therapy		<input type="checkbox"/>	<input type="checkbox"/>

LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY	Tick one
Critical care unit level 3	<input type="checkbox"/>
Critical care unit level 2	<input type="checkbox"/>
Post-anaesthesia care unit	<input type="checkbox"/>
Surgical ward	<input type="checkbox"/>

SECTION 5: 30-DAY FOLLOW-UP



SUBJECT #	_ _ _ - _ _ _ _	SITE #	_ _ _ _ _ _ _ _ _ _ _ _ _
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Date of follow-up	_ _ / _ _ _ _ / _ _ _ _ _ _ _ _ (DD-MMM-YYYY)
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All of the outcomes in section 5 refer to the time period within 30 days of randomisation			
Primary outcome	YES	NO	If yes, date of event
Pneumonia	<input type="checkbox"/>	<input type="checkbox"/>	_ _ / _ _ _ _ / _ _ _ _ _ _ _ _ (DD-MMM-YYYY)
Endotracheal re-intubation	<input type="checkbox"/>	<input type="checkbox"/>	_ _ / _ _ _ _ / _ _ _ _ _ _ _ _ (DD-MMM-YYYY)
Death	<input type="checkbox"/> Alive	<input type="checkbox"/> Dead	Date of death: _ _ / _ _ _ _ / _ _ _ _ _ _ _ _ (DD-MMM-YYYY)

Respiratory complications	I	II	III	IV	V	NONE
Pneumonia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pleural effusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pneumothorax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bronchospasm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aspiration pneumonitis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acute Respiratory Distress Syndrome (ARDS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infective complications	I	II	III	IV	V	NONE
Surgical site infection (superficial)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surgical site infection (deep)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surgical site infection (organ space)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urinary tract infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infection, source uncertain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Laboratory confirmed blood stream infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please refer to the protocol appendix for specific definitions of complications. Please grade complications using the Clavien-Dindo scale as follows:

- I. Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Anti-emetics, anti-pyretics, diuretics, electrolytes or physiotherapy are not considered a deviation from the normal postoperative course.
- II. Requires pharmacological treatment with drugs (including blood transfusion or total parenteral nutrition) other than those excluded from grade I.
- III. Requires surgical, endoscopic or radiological intervention.
- IV. Life-threatening complication (including CNS complication, but excluding transient ischaemic attack) requiring critical care admission
- V. Death

SECTION 5: 30-DAY FOLLOW-UP


SUBJECT #	_ _ _ - _ _ _ _	SITE #	_ _ _ _ _ _ _ _ _ _ _ _ _
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Cardiac complications	I	II	III	IV	V	NONE
Myocardial infarction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Arrhythmia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiogenic pulmonary oedema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac arrest with successful resuscitation				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other complications	I	II	III	IV	V	NONE
Acute kidney injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pulmonary embolism	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stroke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acute psychosis or delirium	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bowel infarction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anastomotic leak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Perforation of viscus (e.g. bowel, gall bladder etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Postoperative haemorrhage						
Gastro-intestinal bleed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other postoperative haemorrhage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any other complication, <i>please give details here:</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Additional treatments	YES	NO
Blood transfusion	<input type="checkbox"/>	<input type="checkbox"/>
Parenteral (intra-venous) nutrition	<input type="checkbox"/>	<input type="checkbox"/>
Endoscopy or interventional radiology procedure	<input type="checkbox"/>	<input type="checkbox"/>
Repeat surgery	<input type="checkbox"/>	<input type="checkbox"/>
If YES, please indicate the reason for repeat surgery		
Infection	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding	<input type="checkbox"/>	<input type="checkbox"/>
Anastomotic leak	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>
Invasive mechanical ventilation after leaving the operating room	<input type="checkbox"/>	<input type="checkbox"/>
If YES, what was the total duration of invasive mechanical ventilation?	_ _ _ hours	
Non-invasive mechanical ventilation after leaving the operating room	<input type="checkbox"/>	<input type="checkbox"/>
If YES, what was the total duration of non-invasive mechanical ventilation?	_ _ _ hours	

SECTION 5: 30-DAY FOLLOW-UP

SUBJECT #	_ _ _ - _ _ _ _	SITE #	_ _ _ _ _ _ _ _ _ _ _ _ _ _
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Patients admitted to a critical care unit	YES	NO
Was the participant admitted to a critical care unit? <i>NB. If 'no', move to the next section.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Was the critical care admission to treat a complication?	<input type="checkbox"/>	<input type="checkbox"/>
Was a planned critical care admission prolonged by a postoperative complication?	<input type="checkbox"/>	<input type="checkbox"/>
What was the total duration of the level 2 critical care stay within 30 days of randomisation?	_ _ days	
What was the total duration of the level 3 critical care stay within 30 days of randomisation?	_ _ days	
Details of the hospital stay	YES	NO
Duration of primary hospital admission (from randomisation)	_ _ days	
Re-admission to hospital within 30 days of randomisation	<input type="checkbox"/>	<input type="checkbox"/>

Investigator self-assessment of blinding	
I was suitably blinded	<input type="checkbox"/>
I may have known the study group allocation	<input type="checkbox"/>
I definitely knew the study group allocation	<input type="checkbox"/>

The self-assessment of blinding should be completed by the investigator that collects the 30-day follow up data. This assessment only applies to data collection at this time point

SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP



SUBJECT #	_ _ _ - _ _ _ _	SITE #	_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _
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ONLY COMPLETE THIS FORM IF THE PATIENT EXPERIENCED AN ADVERSE EVENT DURING CPAP

In the case of multiple adverse events, please complete a separate form for each one.

ADVERSE EVENT RELATED TO CPAP FORM – PAGE 1		NO	YES
Did the patient experience an adverse event related to Continuous Positive Airway Pressure (CPAP) that was delivered as part of the PRISM trial?		<input type="checkbox"/>	<input type="checkbox"/>
If YES, please answer the following questions.			
Date and time of onset of adverse event	_ _ / _ _ _ _ / _ _ _ _ (DD/MMM/YYYY)	_ _ : _ _ (HR:MIN)	
Adverse Event	NO	YES	
Interface intolerance due to excessive air leak	<input type="checkbox"/>	<input type="checkbox"/>	
Pain	<input type="checkbox"/>	<input type="checkbox"/>	
Cutaneous pressure area	<input type="checkbox"/>	<input type="checkbox"/>	
Claustrophobia	<input type="checkbox"/>	<input type="checkbox"/>	
Oronasal dryness	<input type="checkbox"/>	<input type="checkbox"/>	
Hypercapnia	<input type="checkbox"/>	<input type="checkbox"/>	
Haemodynamic instability	<input type="checkbox"/>	<input type="checkbox"/>	
Vomiting	<input type="checkbox"/>	<input type="checkbox"/>	
Aspiration of gastric contents	<input type="checkbox"/>	<input type="checkbox"/>	
Other:	<input type="checkbox"/>	<input type="checkbox"/>	
Response to adverse event	Tick one		
CPAP was <i>unchanged</i>	<input type="checkbox"/>		
CPAP was <i>modified</i>	<input type="checkbox"/>		
CPAP was <i>stopped</i>	<input type="checkbox"/>		
Outcome of adverse event	NO	YES	
If YES to any option below, please notify the PRISM trial coordinating centre within 24 hours by email.			
Death	<input type="checkbox"/>	<input type="checkbox"/>	
Life-threatening complication	<input type="checkbox"/>	<input type="checkbox"/>	
Prolonged hospital stay	<input type="checkbox"/>	<input type="checkbox"/>	
Significant disability or incapacity	<input type="checkbox"/>	<input type="checkbox"/>	

SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP**SUBJECT #**

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SITE #

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ADVERSE EVENT RELATED TO CPAP FORM – PAGE 2

Please describe the adverse event, including any treatment or medication required.

Name and signature:

Date:

