

SECTION 2: BEFORE SURGERY



SUBJECT #	_ _ _ - _ _ _ _	SITE #	_ _ _ _ _ _ _ _ _ _ _ _ _
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CO-MORBID DISEASE		YES	NO
1.	Chronic respiratory disease		
	Chronic obstructive pulmonary disease (COPD)	<input type="checkbox"/>	<input type="checkbox"/>
	Asthma	<input type="checkbox"/>	<input type="checkbox"/>
	Interstitial lung disease or pulmonary fibrosis	<input type="checkbox"/>	<input type="checkbox"/>
	Bronchiectasis	<input type="checkbox"/>	<input type="checkbox"/>
2.	Ischaemic heart disease	<input type="checkbox"/>	<input type="checkbox"/>
3.	Diabetes mellitus	<input type="checkbox"/>	<input type="checkbox"/>
4.	Heart failure	<input type="checkbox"/>	<input type="checkbox"/>
5.	Liver cirrhosis	<input type="checkbox"/>	<input type="checkbox"/>
6.	Active cancer	<input type="checkbox"/>	<input type="checkbox"/>
	If yes – is cancer the indication for surgery?	<input type="checkbox"/>	<input type="checkbox"/>
	If yes - is the surgery intended to be: <input type="checkbox"/> curative or <input type="checkbox"/> palliative		
7.	Previous stroke or transient ischaemic attack (TIA)	<input type="checkbox"/>	<input type="checkbox"/>
8.	Current smoker (within the last 14 days)?	<input type="checkbox"/>	<input type="checkbox"/>
9.	Primary respiratory infection within the previous month (including acute pulmonary tuberculosis)?	<input type="checkbox"/>	<input type="checkbox"/>
10.	Diagnosis of Human Immunodeficiency Virus (HIV) infection? <i>NB. If not tested please tick 'no'.</i>	<input type="checkbox"/>	<input type="checkbox"/>

OTHER DETAILS			
Fødselsnummer	_ _ _ _ _ - _ _ _ _ _		
ASA (American Society of Anesthesiologists) physical status class			
Class I <input type="checkbox"/>		Class II <input type="checkbox"/>	
Class III <input type="checkbox"/>		Class IV <input type="checkbox"/>	
		Class V <input type="checkbox"/>	
Physical measurements			
Height (cm):	_ _ _	Weight (kg):	_ _ _
Resting oxygen saturation (SpO ₂):		_ _ _ %	
Laboratory values (within 4 weeks before surgery)			Tick if NOT measured
Haemoglobin measurement	_ _ _ g/dL	<input type="checkbox"/>	
Creatinine measurement	_ _ _ μmol/L	<input type="checkbox"/>	
Ethnicity (for eGFR)	Black or Afro-Caribbean <input type="checkbox"/>	Other <input type="checkbox"/>	

SECTION 3: DURING SURGERY

SUBJECT #

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SITE #

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START OF SURGERYDATE: |_|_|_|/|_|_|_|_|_|/|_|_|_|_|_|_|_|_|_|_|_|_|_|_|
(DD/MMM/YYYY)TIME: |_|_|_| : |_|_|_|
(HR : MINS)

SURGICAL PROCEDURE PERFORMED (single most appropriate)	Tick one	
Resection of colon, rectum or small bowel	<input type="checkbox"/>	
Resection of liver, pancreas or gall bladder	<input type="checkbox"/>	
Resection of stomach (non-obesity surgery)	<input type="checkbox"/>	
Resection of oesophagus (non-obesity)	<input type="checkbox"/>	
Obesity surgery	<input type="checkbox"/>	
Vascular procedure	<input type="checkbox"/>	
Other intra-peritoneal surgery	<input type="checkbox"/>	
SURGICAL TECHNIQUE	YES	NO
Open surgical technique used during surgery	<input type="checkbox"/>	<input type="checkbox"/>
ANAESTHETIC TECHNIQUE		
General Anaesthesia	<input type="checkbox"/>	<input type="checkbox"/>
Epidural anaesthesia	<input type="checkbox"/>	<input type="checkbox"/>
Spinal anaesthesia	<input type="checkbox"/>	<input type="checkbox"/>
Did the patient have an endotracheal tube inserted?	<input type="checkbox"/>	<input type="checkbox"/>
If YES, was the patient extubated before leaving the operating room?	<input type="checkbox"/>	<input type="checkbox"/>
MECHANICAL VENTILATION DURING SURGERY		
Did the patient receive a recruitment manoeuvre during surgery?	<input type="checkbox"/>	<input type="checkbox"/>
Did the patient receive mechanical ventilation during surgery?	<input type="checkbox"/>	<input type="checkbox"/>
If YES, please answer the following:		
Maximum positive end-expiratory pressure (PEEP)	_ _ _ cmH ₂ O	
Maximum set tidal volume (Vt)	_ _ _ _ ml	
Maximum respiratory rate	_ _ _ min ⁻¹	
Maximum FiO ₂ (excluding pre-oxygenation during induction of anaesthesia)	_ _ _ %	
INTRAVENOUS FLUIDS DURING SURGERY		
Total volume of intravenous fluid administered excluding blood products	_ _ _ _ _ mL	
Total volume of blood products administered	_ _ _ _ _ mL	
Date and time of the end of surgery	_ _ _ / _ _ _ _ _ / _ _ _ _ _ _ _ _ _ _ _ _ _ _ (DD/MMM/YYYY)	_ _ _ : _ _ _ (HR:MIN)

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 #

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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 #**

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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

SECTION 6: ONE-YEAR FOLLOW-UP**SUBJECT #**

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SITE #

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Date of follow-up|_|_|_|/|_|_|_|_|_|/|_|_|_|_|_|
(DD-MMM-YYYY)**Patient status on date of follow-up** Alive Dead: date of death: |_|_|_|/|_|_|_|_|_|/|_|_|_|_|_|
(DD-MMM-YYYY)

SUPPLEMENTARY FORM: WITHDRAWAL**SUBJECT #**

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SITE #

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ONLY COMPLETE THIS FORM IF THE PARTICIPANT PREMATURELY STOPPED THEIR PARTICIPATION IN THE TRIAL OR IF THEY COULD NOT BE CONTACTED

Date the patient prematurely discontinued study participation:

|_|_|_|/|_|_|_|_|/|_|_|_|_|
(DD-MMM-YYYY)

What was the primary reason for the discontinuation of the study?

- Inclusion/Exclusion criteria not fulfilled
- Surgical procedure abandoned
- Adverse event related
- Patient initiated
- Other, specify:

In the case of patient withdrawal, please check:

- The participant agrees that any data collected up to the date of withdrawal can still be used.
- The patient would like their data removed from the database.

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:

SUPPLEMENTARY FORM: PROTOCOL DEVIATION



SUBJECT #

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SITE #

_ _

ONLY COMPLETE THIS FORM IF THERE IS A PROTOCOL DEVIATION

Participant in the intervention group did **NOT** receive CPAP

NB. This includes instances where CPAP is started more than twelve hours after the end of surgery. If CPAP was administered, but for only a brief duration, please record this in the next section below.

Please indicate the reason

CPAP was not offered	<input type="checkbox"/>
Participant remained intubated after surgery	<input type="checkbox"/>
Inadequate staffing or process issues	<input type="checkbox"/>
Participant or clinician refusal	<input type="checkbox"/>
Participant was too unwell to receive CPAP	<input type="checkbox"/>
Equipment failure	<input type="checkbox"/>
Other (please state):	<input type="checkbox"/>

CPAP administered for less than 4 hours duration

NB. This includes instances where CPAP was administered, but only for a brief duration

Please indicate the reason

Participant or clinician refusal	<input type="checkbox"/>
Inadequate staffing or process issues	<input type="checkbox"/>
Participant too unwell to continue with CPAP	<input type="checkbox"/>
Equipment failure	<input type="checkbox"/>
Other (please state):	<input type="checkbox"/>

CPAP administered with significant interruption

NB. Brief interruptions to adjust mask, or for oral/nursing care are considered part of the intervention and do not require a protocol deviation form to be completed

Please indicate the reason

Participant or clinician refusal	<input type="checkbox"/>
Inadequate staffing or process issues	<input type="checkbox"/>
Participant too unwell to continue with CPAP	<input type="checkbox"/>
Equipment failure	<input type="checkbox"/>
Other (please state):	<input type="checkbox"/>

