# SECTION 1: INCLUSION, EXCLUSION & RANDOMISATION INFORMATION

SUBJECT #



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DEMOGRAPHIC INFORMATION						
Given name		Family name		_		
Date of birth	_ /  _ /  _ _  _  (DD/MMM/YYYY)	Gender	Female	Male 🗆		
Consent date	/   /      (DD/MMM/YYYY)	Date of surgery	_ /   /   _ _			

INCLUSION & EXCLUSION CRITERIA	YES	NO
Age ≥ 50 years		
Planned elective major intra-peritoneal surgery using an open surgical technique		
Inability or refusal to provide informed consent		
Anticipated requirement for invasive or non-invasive mechanical ventilation for at least four hours after surgery as part of routine care		
Known or suspected pregnancy or planned obstetric surgery		
Previous enrolment in the PRISM trial		
Current participation in another clinical trial of a treatment with a similar biological mechanism or primary outcome measure		
Clinician refusal (concern specific to surgical procedure)		
Clinician refusal (other)		
Contraindication to continuous positive airway pressure (CPAP)		

Planned level of care on the first night after surgery	Tick one
Critical care unit level 3	
Critical care unit level 2	
Post-anaesthesia care unit	
Surgical ward	

RANDOMISATION CRITERIA	Tick	one			
Planned surgical procedure (single most appropriate)					
Resection of colon, rectum or small bowel					
Resection of liver, pancreas or gall bladder					
Resection of stomach (non-obesity surgery)					
Resection of oesophagus (non-obesity surgery)					
Obesity surgery					
Vascular procedure					
Other intra-peritoneal surgery					
Planned anaesthetic technique	YES NO				
Planned use of epidural anaesthesia					
Randomisation should only take place once it is certain that surgery	will take pla	ce			

<b>SECTION 2</b>	: BEFORE SURGERY			
SUBJECT #	- - -	SITE #	_ _ _ _ _ _ _ _	

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

OTHER DETAILS								
Hospital number  _ _ _ _ _ _ _								
ASA (American Society of Anesthesiologists) physical status class								
Class I 🗆	Class II 🗆	Class III 🗆	Class IV $\Box$	Class '	V□			
Physical measurements								
Height (cm):			Weight (kg):  _ _					
Resting	oxygen saturation (SpC	<b>D</b> <sub>2</sub> ):		_	%			
Laboratory values	(within 4 weeks before	e surgery)			Tick if NOT measured			
Haemoglobin measurement			∣ g/dL					
Creatinine measu	rement	_	µmol/L					
Ethnicity (for eGF	R)	I	Black or Afro-Carribe	an 🗆	Other			

SECTION 3: DURING SURGERY						
SUBJECT #		_	SITE #		_	
START OF S	URGERY	DAT		/     /MMM/YYYY)	TIME:   _  :    (HR : MINS)	

SURGICAL PROCEDURE PERFORMED (single most a	appropriate)	Tick o	ne
Resection of colon, rectum or small bowel			
Resection of liver, pancreas or gall bladder			
Resection of stomach (non-obesity surgery)			
Resection of oesophagus (non-obesity)			
Obesity surgery			
Vascular procedure			
Other intra-peritoneal surgery			
SURGICAL TECHNIQUE		YES	NO
Open surgical technique used during surgery			
ANAESTHETIC TECHNIQUE			
General Anaesthesia			
Epidural anaesthesia			
Spinal anaesthesia			
Did the patient have an endotracheal tube inserted?			
If YES, was the patient extubated before leaving the op	perating room?		
MECHANICAL VENTILATION DURING SURGERY			
Did the patient receive a recruitment manoeuvre during su	urgery?		
Did the patient receive mechanical ventilation during surg	ery?		
If YES, please answer the following:			
Maximum positive end-expiratory pressure (PEEP	)	cr	mH₂O
Maximum set tidal volume (Vt)			ml
Maximum respiratory rate		_  r	min⁻¹
Maximum FiO <sub>2</sub> (excluding pre-oxygenation during	induction of anaesthesia)	_	_  %
INTRAVENOUS FLUIDS DURING SURGERY			
Total volume of intravenous fluid administered excluding b	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 #	<sup>_</sup>	SITE #					
CPAP AFTER SURGERY YES NO					NO		
Did the patient receive Continuous Positive Airway Pressure (CPAP) started within twelve hours after the end of surgery?							
If YES, please answer the following questions. If NO, please skip to next section.							

Date and time patient started CPAP	/   /      (DD/MMM/YYYY)	<b>:</b> (HR:M	I — — I — — I
Total duration of CPAP within twelve hours	_ _  (MINS)		
Maximum airway pressure received during	this period		∣ cmH₂O
Primary method of CPAP delivery (single m	nost appropriate)		
Face mask			]
Helmet device			]
Nasal mask			]
		YES	NO
Were extra research staff present to help d	eliver CPAP?		
Did the staff administering CPAP use equip	oment to monitor airway pressures?		
Did the staff administering CPAP use equip	oment to monitor the FiO <sub>2</sub> ?		
Did the patient have a nasogastric tube in s	situ during CPAP?		

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				
Non-invasive mechanical ventilation				
High flow nasal oxygen therapy				

LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY	Tick one
Critical care unit level 3	
Critical care unit level 2	
Post-anaesthesia care unit	
Surgical ward	

SECTION 5: 30-DAY FOLLOW-UP					
SUBJECT #	•	SITE #			

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			/   /      (DD-MMM-YYYY)				
Endotracheal re-intubation			/   /      (DD-MMM-YYYY)				
Death	□ Alive	□ Dead	Date of death:   _ /  _ /  _  _  _   (DD-MMM-YYYY)				

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

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, diruetics, 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 #			_		_		
Cardiac complications	I		II		IV	V	NONE
Myocardial infarction							
Arrhythmia							
Cardiogenic pulmonary oedema							
Cardiac arrest with successful resuscitation							
Other complications	I		II	III	IV	V	NONE
Acute kidney injury							
Pulmonary embolism							
Stroke							
Acute psychosis or delirium							
Bowel infarction							
Anastomotic leak							
Perforation of viscus (e.g. bowel, gall bladder etc)							
Postoperative haemorrhage							
Gastro-intestinal bleed							
Other postoperative haemorrhage							
Any other complication, please give details here:							
	1	I		1	1	1	· ]

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

<b>SECTION 5</b>	: 30-DAY FOLLOW-U	C		
SUBJECT #	<sup>_</sup>	SITE #		

Patients admitted to a critical care unit	YES	NO
Was the participant admitted to a critical care unit? NB. If 'no', move to the next section.		
Was the critical care admission to treat a complication?		
Was a planned critical care admission prolonged by a postoperative complication?		
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		

Investigator self-assessment of blinding					
I was suitably blinded					
I may have known the study group allocation					
I definitely knew the study group allocation					

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 #	III <sup>_</sup> IIII	SITE #		_		
Date of follo	w-up	/   /     (DD-MMM-YYYY)				
Patient statu	is on date of follow-up	□ Alive □ De	ad: date of death:	_ /   /  (DD-MMM-YYYY)	_	

SUPPLEMETARY FORM: WITHDRAWAL					
SUBJECT #	+  -	SITE #			

# 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?	<ul> <li>Inclusion/Exclusion criteria not fulfilled</li> <li>Surgical procedure abandoned</li> <li>Adverse event related</li> <li>Patient initiated</li> <li>Other, specify:</li> </ul>
In the case of patient withdrawal, please check:	<ul> <li>The participant agrees that any data collected up to the date of withdrawal can still be used.</li> <li>The patient would like their data removed from the database.</li> </ul>

SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP				
SUBJECT #	<b>-</b>	SITE #		

#### 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?			
If YES, please answer the following questions.			
Date and time of onset of adverse event          /  //	_ : (HR:N		
Adverse Event	NO	YES	
Interface intolerance due to excessive air leak			
Pain			
Cutaneous pressure area			
Claustrophobia			
Oronasal dryness			
Hypercapnia			
Haemodynamic instability			
Vomiting			
Aspiration of gastric contents			
Other:			
Response to adverse event	Tick	one	
CPAP was unchanged		]	
CPAP was <i>modified</i>		]	
CPAP was <b>stopped</b>		]	
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			
Life-threatening complication			
Prolonged hospital stay			
Significant disability or incapacity			

SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP				
SUBJECT #	- - -	SITE #	_ _ _ _ _ _ _ _ _ _	

## 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 #	<sup>_</sup>	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		
Participant remained intubated after surgery		
Inadequate staffing or process issues		
Participant or clinician refusal		
Participant was too unwell to receive CPAP		
Equipment failure		
Other (please state):		

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		
Inadequate staffing or process issues		
Participant too unwell to continue with CPAP		
Equipment failure		
Other (please state):		

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		
Inadequate staffing or process issues		
Participant too unwell to continue with CPAP		
Equipment failure		
Other (please state):		

SUPPLEMENTARY FORM: PROTOCOL DEVIATION				
SUBJECT #	+  +	SITE #		

CPAP started at a dose other than 5cmH <sub>2</sub> O	
Please indicate the reason	
Communication error	
Decision by clinical staff	
Other (please state):	

Participant in the usual care group <i>DID</i> receive CPAP	
Please indicate the reason	
Randomisation	
Communication error	
Decision by clinical staff	
Other (please state):	

Other protocol deviation	
Other (please state):	

## PROTOCOL DEVIATION

Briefly describe the protocol deviation.

Name and	signature:
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Date: