Screening version 1.1

Title: Screening

Instructions:

SCREENING FORM

PATIENT IDENTIFICATION

S1 National identification number [_____] [info]

Date of birth (ddmmyy) [_____]   Site ID [_____]   Serial [_____]

INCLUSION CRITERIA

S2 Acutely admitted to the ICU? ○ Yes ○ No [info]

S3 Age ≥ 18 years? ○ Yes ○ No

S4 Respiratory support in a **closed system** with an $FiO_2 \geq 0.50$? ○ Yes ○ No [info]

S5 Oxygen supplementation through an **open system** with a oxygen flow of ≥ 10 L/min?
(See definition in info-box) ○ Yes ○ No [info]

S6 Oxygen supplementation in the ICU expected to last for at least 24 hours?
(If in doubt of this forecast answer 'YES') ○ Yes ○ No [info]

S7 Intraarterial catheter in place? ○ Yes ○ No [info]

EXCLUSION CRITERIA

S8 More than 12 hours since admission to the ICU? ○ Yes ○ No [info]

S9 Chronic mechanical ventilation? ○ Yes ○ No [info]

S10 Use of home oxygen supplementation? ○ Yes ○ No [info]

S11 Previously treated with bleomycin? ○ Yes ○ No [info]

S12 Solid organ transplant planned or conducted during current hospitalisation? ○ Yes ○ No [info]

S13	Withdrawal from active therapy or brain death deemed imminent?	○ Yes ○ No
S14	Known pregnancy?	○ Yes ○ No [info]
S15	Poisoned with carbon monoxide, cyanide or paraquat?	○ Yes ○ No [info]
S16	Methaemoglobinaemia?	○ Yes ○ No [info]
S17	Sickle cell disease?	○ Yes ○ No [info]
S18	Condition expected to involve the use of hyperbaric oxygen treatment (HBO)?	○ Yes ○ No [info]
S19	Consent according to national regulations NOT obtainable?	○ Yes ○ No [info]

STRATIFICATION VARIABLES

S20	Name of the patient	[_____] [info]
S21	Chronic obstructive pulmonary disease (COPD)?	○ Yes ○ No [info]
S22	Active haematological malignancy?	○ Yes ○ No [info]
S23	Site ID	[_____]
S24	Participant randomised to	[_____]
S25	Randomisation timestamp	[_____]

Baseline (44/44)

Title: Baseline
Instructions:

<div style="background-color:green; text-align:center">

BASELINE FORM

</div>

General Patient Information

B1	Sex?	○ Male ○ Female [info]
B2	Hospital admission date?	[_____] 📅 (dd-mm-yyyy) [info]
B3	ICU admission date?	[_____] 📅 (dd-mm-yyyy) [info]
B4	ICU admission time?	[_____] (hh:mm, 24 hours format) [info]
B5	ICU admission was directly from the operating or recovery room after surgery?	○ Yes ○ No
B5a	Type of surgery leading to ICU admission?	○ Elective ○ Acute [info]
B6	Patient height? *Choose unit first*	○ cm ○ feet / inches [_____] (cm) [_____] (feet) [_____] (inches) [info]

Respiratory Support

B7	Type of closed respiratory support system at randomisation?	○ Invasive MV ○ NIV or CPAP [info]
B7a	TV at randomisation?	[_____] (mL) [info]
B7b	PEEP at randomisation?	[_____] (cmH_2O) [info] ☐ Not Available
B7c	P_{peak} at randomisation?	[_____] (cmH_2O) [info]
B7d	EPAP or CPAP pressure at randomisation?	[_____] (cmH_2O) [info]

Arterial Blood Gas
before randomisation

B8	PaO_2 in the last ABG before randomisation?	○ kPa ○ mmHg [_____] [info] ☐ Not Available
B9	SaO_2 in the last ABG before randomisation?	[_____] (%) [info] ☐ Not Available
B10	p-lactate in the last ABG before randomisation?	[_____] (mmol/L) [info] ☐ Not Available
B11	FiO_2 at the time of the last ABG?	[_____] [info]

Acute Illness

B12	Pneumonia?	○ Yes ○ No [info]
B13	Multiple trauma?	○ Yes ○ No [info]
B14	Stroke (haemorrhagic or ischaemic)?	○ Yes ○ No [info]
B15	Traumatic brain injury?	○ Yes ○ No [info]
B16	Myocardial infarction?	○ Yes ○ No [info]

EX1	Cardiac arrest before randomisation?	○ Yes ○ No [info]
B17	Intestinal ischaemia?	○ Yes ○ No [info]
B18	ARDS at randomisation?	○ Yes ○ No [info]

SOFA (Sequential Organ Failure Assessment) Score

B19	Lowest Glasgow coma score in the 24 hours prior to randomisation? *If sedated, estimate the last score before sedation. If unknown write 15*	[_____] [info]
B20	Lowest MAP in 24 hours prior to randomisation?	[_____] (mmHg) [info]
B21	Use of dobutamine, milrinone and/or levosimendan within 24 hours before the randomisation?	○ Yes ○ No [info]
B22	Use of any continuous infusion of vasopressors in the 24 hours prior to randomisation?	○ Yes ○ No [info]
B22a	Highest dose of dopamine in the 24 hours prior to randomisation? *If dopamine has not been used write 0*	[_____] (µg/kg/min) [info]
B22b	Highest dose of norepinephrine (noradrenalin) in the 24 hours prior to randomisation? *If norepinephrine has not been used write 0*	[_____] (µg/kg/min) [info]
B22c	Highest dose of epinephrine (adrenalin) in the 24 hours prior to randomisation? *If epinephrine has not been used write 0*	[_____] (µg/kg/min) [info]
B23	Highest concentration of bilirubin in 24 hours prior to randomisation?	[_____] (µmol/L) [info] ☐ Not Available
B24	Lowest concentration of platelets in 24 hours prior to randomisation?	[_____] (x10^9/L) [info] ☐ Not Available
B25	Urinary output in the 24 hours prior to randomisation? *If urine volume is measured for a short period MULTIPLY TO GET TOTAL OUTPUT IN 24 hours!*	[_____] (mL) [info] ☐ Not Available
B26	Highest creatinine in the 24 hours prior to randomisation?	[_____] (µmol/L) [info] ☐ Not Available

Chronic Co-morbidities

B27	History of ischaemic heart disease?	○ Yes ○ No [info]
B28	Chronic heart failure?	○ Yes ○ No [info]
B29	Active metastatic cancer?	○ Yes ○ No [info]
B30	Chronic dialysis?	○ Yes ○ No [info]
B30a	Habitual creatinine level > 110 µmol/L?	○ Yes ○ No [info]

Daily Form version 1.0

Title: Daily Form

Instructions:

DAILY FORM

Time Span

Site ID _____

Day start date: _____   Day start time: _____

Day end date: _____   Day end time: _____

Respiration

D1   Respiratory support on this day?   ○ Yes ○ No [info]

D1a Use of mechanical ventilation in **prone position** in the ICU on this day?   ○ Yes ○ No [info]

D1b Use of **inhaled vasodilators** during mechanical ventilation on this day?   ○ Yes ○ No [info]

D1c Use of **ECMO** in the ICU on this day?   ○ Yes ○ No [info]

06:00h to 18:00h

D2   Highest PaO_2 from 06:00h to 18:00h?   ○ kPa ○ mmHg _____ [info] ☐ Not Available

D2a SaO_2 in the ABG with the **highest** PaO_2 from 06:00h to 18:00h   _____ (%) [info]

D2b FiO_2 at the time of the ABG with the **highest** PaO_2 from 06:00h to 18:00h   _____ [info]

D3   Lowest PaO_2 from 06:00h to 18:00h?   ○ kPa ○ mmHg _____ [info]

D3a SaO_2 in the ABG with the **lowest** PaO_2 from 06:00h to 18:00h   _____ (%) [info]

D3b FiO_2 at the time of the ABG with the **lowest** PaO_2 from 06:00h to 18:00h   _____ [info]

ABGs

D6   Total number of ABGs on this day?   _____ [info]

Respiratory status 08:00

D7   Did the patient receive respiratory support at 08:00h on this day?   ○ Yes ○ No [info]

D7a Type of respiratory support at 08:00h?   ○ Invasive MV ○ NIV or CPAP [info]

D7a1 TV at 08:00h?   _____ (mL) [info]

D7a2 PEEP at 08:00h?   _____ (cmH$_2$O) [info] ☐ Not Available

D7a3 P_{peak} at 08:00h?   _____ (cmH$_2$O) [info]

D7a4 EPAP or CPAP pressure at 08:00h?   _____ (cmH$_2$O) [info]

Remaining organ systems

D8	Highest p-lactate on this day?	_____ (mmol/L) [info] ☐ Not Available
D9	Circulatory support (infusion of vasopressor/inotropes) on this day?	○ Yes ○ No [info]
D10	Renal replacement therapy on this day?	○ Yes ○ No [info]
D11	New myocardial ischaemia on this day?	○ Yes ○ No [info]
D11a	Was this myocardial ischaemia related to the allocated oxygenation target?	○ Yes, related ○ Possibly related ○ No, not related
D12	Cerebral CT or MR scan on this day with signs of **new** ischaemic stroke?	○ Yes ○ No [info]
D12a	Was this ischaemic stroke related to the allocated oxygenation target?	○ Yes, related ○ Possibly related ○ No, not related
D13	New intestinal ischaemia on this day?	○ Yes ○ No [info]
D13a	Was this intestinal ischaemia related to the allocated oxygenation target?	○ Yes, related ○ Possibly related ○ No, not related
D14	Number of units of red blood cells transfused on this day?	_____ (Units) [info]

Withdrawal version 1.0

Title: Withdrawal

Instructions:

WITHDRAWAL FORM

WITHDRAWAL FROM INTERVENTION AND/OR DATA REGISTRATION

W1	Date of withdrawal?	⬚ (dd-mm-yyyy)
W2	Time of withdrawal? (24 hours)	(hh:mm)
W3	Reason for withdrawal?	○ SUSAR [info] ○ Consent not given or withdrawn
W3a	Who is not giving or withdrawing consent?	○ Relative/next of kin/guardian not giving or withdrawing consent ○ Patient not giving or withdrawing consent
W3b	Will further daily data be registered?	○ Yes ○ No

Discharge and readmission version 1.0

Discharge and readmission

Title: Discharge and readmission

Instructions:

DISCHARGE AND READMISSION FORM						
Date of ICU readmission (dd-mm-yyyy)	**Time of ICU readmission (hh:mm, 24 hours format)**	**Date of ICU discharge (dd-mm-yyyy)**	**Time of ICU discharge (hh:mm, 24 hours format)**	**Patient discharged to** [info]	**Has the patient been enrolled in other interventional trials during this ICU admission**	**Patient transferred to site Id**
				○ General Ward ○ ICU participating in HOT-ICU trial ○ ICU not participating in HOT-ICU trial ○ Home (including nursing homes and similar) ○ Dead	○ Yes ○ No	

Follow-Up 90 days version 1.0

Title: Follow-up 90 days

Instructions:

90 DAYS FOLLOW-UP

F0	Date of follow-up		Calculated as 90 days after randomisation
F1	Discharged from hospital within 90 days?	○ Yes [info] ○ No	
	F1a Date of discharge from hospital?		(dd-mm-yyyy)
	F1b Readmitted to hospital within 90 days?	○ Yes [info] ○ No	
	F1b1 Days in hospital during readmission(s)?		(days) [info]
F2	Renal replacement therapy **outside** the ICU in the 90 days of follow-up?	○ Yes [info] ○ No	
	F2a Date of last renal replacement therapy **outside** the ICU?		(dd-mm-yyyy) [info]
	F2a1	☐ Renal replacement therapy ongoing at 90-day follow-up	
F3	Did the patient die within 90 days of follow-up?	○ Yes [info] ○ No	
F3a	Date of death?		(dd-mm-yyyy)

Follow-Up 1 year version 1.0

Follow-Up 1 year

Title: Follow-up 1 year
Instructions:

1 YEAR FOLLOW-UP

F4	Date of follow-up		Calculated as 365 days after randomisation

Mortality

F5	Was the patient dead at one-year follow-up?	○ Yes [info] ○ No

EuroQol

F6	Lost to EuroQol follow-up?	○ Yes [info] ○ No

F7	Date of EQ-5D-5L and EQ-vas interviews	

F8	EQ-5D-5L score **Mobility**?	○ I have no problems in walking about [info] ○ I have slight problems in walking about ○ I have moderate problems in walking about ○ I have severe problems in walking about ○ I am unable to walk about ○ The answer is not obtainable

F9	EQ-5D-5L score **Self-care**?	○ I have no problems with washing or dressing myself [info] ○ I have slight problems with washing or dressing myself ○ I have moderate problems with washing or dressing myself ○ I have severe problems with washing or dressing myself ○ I am unable to wash or dress myself ○ The answer is not obtainable

F10	EQ-5D-5L score **Usual activities**?	○ I have no problems doing my usual activities [info] ○ I have slight problems doing my usual activities ○ I have moderate problems doing my usual activities ○ I have severe problems doing my usual activities ○ I am unable to do my usual activities ○ The answer is not obtainable

F11	EQ-5D-5L score **Pain/discomfort**?	○ I have no pain or discomfort [info] ○ I have slight pain or discomfort ○ I have moderate pain or discomfort ○ I have severe pain or discomfort ○ I have extreme pain or discomfortf ○ The answer is not obtainable

F12	EQ-5D-5L score **Anxiety/depression**?	○ I am not anxious or depressed [info] ○ I am slighty anxious or depressed ○ I am moderately anxious or depressed ○ I am severely anxious or depressed ○ I am extremely anxious or depressed ○ The answer is not obtainable

F13	EQ-VAS score (1-100)?		[info]