Screening version 1.1

Title: Screening

Instructions:

<div style="background:green">

SCREENING FORM

</div>

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?   ○ Yes ○ No [info]

(See definition in info-box)

S6   Oxygen supplementation in the ICU expected to last for at least 24 hours?   ○ Yes ○ No [info]

(If in doubt of this forecast answer 'YES')

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 (0/47)

Title: Baseline

Instructions:

BASELINE FORM

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$_2$O) [info]   ☐ Not Available

B7c   P$_{peak}$ at randomisation?   [_____] (cmH$_2$O) [info]

B7d   EPAP or CPAP pressure at randomisation?   [_____] (cmH$_2$O) [info]

Arterial Blood Gas
before randomisation

B8   PaO$_2$ in the last ABG before randomisation?   ○ kPa ○ mmHg   [*Choose unit first*] [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] ☐ Estimated
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] ○ Estimated < 200 ml ○ Estimated 200-500 ml ○ Estimated > 500 ml
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] ☐ Estimated

Daily Form v. 1.1

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]

18:00h to 06:00h

D4   Highest PaO_2 from 18:00h to 06:00h?   ◯ kPa ◯ mmHg _____ [info]   ☐ Not Available

   D4a SaO_2 in the ABG with the **highest** PaO_2 from 18:00h to 06:00h   _____ (%) [info]

   D4b FiO_2 at the time of the ABG with the **highest** PaO_2 from 18:00h to 06:00h   _____ [info]

D5   Lowest PaO_2 from 18:00h to 06:00h?   ◯ kPa ◯ mmHg _____ [info]

   D5a SaO_2 in the ABG with the **lowest** PaO_2 from 18:00h to 06:00h   _____ (%) [info]

   D5b FiO_2 at the time of the ABG with the **lowest** PaO_2 from 18:00h to 06:00h   _____ [info]

ABGs

D6	Total number of ABGs on this day?	[input field]	[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?	[input field] (mL) [info]
D7a2	PEEP at 08:00h?	[input field] (cmH_2O) [info] ☐ Not Available
D7a3	P_{peak} at 08:00h?	[input field] (cmH_2O) [info]
D7a4	EPAP or CPAP pressure at 08:00h?	[input field] (cmH_2O) [info]

Remaining organ systems

D8	Highest p-lactate on this day?	[input field] (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?	[input field] (Units) [info]

Withdrawal version 1.0

Title: Withdrawal

Instructions:

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WITHDRAWAL FORM

</div>

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]