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 ≥ 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 version 1.2

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? ○ cm ○ feet / inches [_____] (cm) [_____] (feet) [_____] (inches) [info]
Choose unit first

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 [*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**   ◯ Yes ◯ No [info]
     position in the ICU on this day?

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

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**   [_____] (%) [info]
          PaO_2 from 06:00h to 18:00h

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

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

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

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

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**   [_____] (%) [info]
          PaO_2 from 18:00h to 06:00h

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

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

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

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

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:

<table>
<tr><td colspan="7" style="background:#00ff00;text-align:center">DISCHARGE AND READMISSION FORM</td></tr>
<tr>
<th>Date of ICU readmission (dd-mm-yyyy)</th>
<th>Time of ICU readmission (hh:mm, 24 hours format)</th>
<th>Date of ICU discharge (dd-mm-yyyy)</th>
<th>Time of ICU discharge (hh:mm, 24 hours format)</th>
<th>Patient discharged to [info]</th>
<th>Has the patient been enrolled in other interventional trials during this ICU admission</th>
<th>Patient transferred to site Id</th>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>
○ General Ward
○ ICU participating in HOT-ICU trial
○ ICU not participating in HOT-ICU trial
○ Home (including nursing homes and similar)
○ Dead
</td>
<td>○ Yes
○ No</td>
<td></td>
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</tr>
</table>

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 1.2

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

F6a   Reason for lost to EuroQol follow-up
- ○ Unable to get hold of the patient
- ○ Patient did not wish to participate
- ○ Other

F6b   Please specify other reason
[_____]

F7   Date of EQ-5D-5L and EQ-vas interviews
[_____] 📅

F8   EQ-5D-5L score **Mobility**?   [info]
- ○ I have no problems in walking about
- ○ 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**?   [info]
- ○ I have no problems with washing or dressing myself
- ○ 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**?   [info]
- ○ I have no problems doing my usual activities
- ○ 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**?   [info]
- ○ I have no pain or discomfort
- ○ 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**?   [info]
- ○ I am not anxious or depressed
- ○ 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]

F14   EuroQol follow-up conducted by proxy?
- ○ Yes [info]
- ○ No