Screening form version 1.0

Title: Screening

Exit (no save)

SCREENING FORM

Support: mail or +45 2118 2543

Patient Identification

S1	National identification number		[info]

Inclusion criteria

S2	Acutely admitted to the ICU?	○ Yes ○ No	[info]
S3	Age ≥ 18 years?	○ Yes ○ No	
S4	Respiratory support in a closed system independent of FiO_2 **OR** oxygen supplementation in an open system with at least 10 L oxygen per minute?	○ Yes ○ No	[info]
S5	Oxygen supplementation in the ICU expected to last for at least 24 hours? *(If in doubt of this forecast answer 'YES')*	○ Yes ○ No	[info]
S6	Intraarterial catheter in place?	○ Yes ○ No	[info]
S7	Positive test for coronavirus?	○ 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]

Form is incomplete

Stratification and randomisation

S20	Name of the patient		[info] ☐ Unknown at the time of screening
S21	Site ID	DK01	
		Perform randomisation	
R1	Participant randomised to		
R2	Randomisation timestamp		

Return to top   **Save**   **Exit (no save)**

Baseline form version 1.0

Baseline (0/50)

Title: Baseline

Instructions:

<table>
<tr><td colspan="2" style="background:yellow">BASELINE FORM
Support: mail or +45 2118 2543</td></tr>
</table>

General patient information

Randomisation timestamp: 15-03-2020 12:44:24

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]

Oxygen supplementation

B7	Type of oxygen supplementation system at randomisation?	○ Closed system [info] ○ Open system

Respiratory Support

B7a	Type of closed respiratory support system at randomisation?	○ Invasive MV ○ NIV or CPAP [info]
B7a1	TV at randomisation?	[_____] (mL) [info]
B7a2	PEEP at randomisation?	[_____] (cmH$_2$O) ☐ Not Available [info]
B7a3	P$_{peak}$ at randomisation?	[_____] (cmH$_2$O) [info]
B7a4	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]	☐ Not Available [info]
B9	SaO_2 in the last ABG before randomisation?	[ ] (%)	☐ Not Available [info]
B10	p-lactate in the last ABG before randomisation?	[ ] (mmol/L)	☐ Not Available [info]
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]

B23	Highest concentration of bilirubin in 24 hours prior to randomisation?	_____ (µmol/L)	☐ Not Available [info]
B24	Lowest concentration of platelets in 24 hours prior to randomisation?	_____ (x10^9/L)	☐ Not Available [info]

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)	☐ Not Available [info]

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
B31	Chronic obstructive pulmonary disease (COPD)?	○ Yes ○ No [info]
B32	Active haematological malignancy?	○ Yes ○ No [info]

Day form version 1.0

Title: Day form

Instructions:

DAY FORM

Support: mail or +45 2118 2543

Site ID	DK01			
Day start date:	18-03-2020	Day start time:	06:00	
Day end date:	18-03-2020	Day end time:	12:35	

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 12:35h

D2	Highest PaO$_2$ from 06:00h to 12:35h?	○ kPa ○ mmHg Choose unit first ☐ Not Available [info]
D2a	SaO$_2$ in the ABG with the **highest** PaO$_2$ from 06:00h to 12:35h	(%) [info]
D2b	FiO$_2$ at the time of the ABG with the **highest** PaO$_2$ from 06:00h to 12:35h	[info]
D3	Lowest PaO$_2$ from 06:00h to 12:35h?	○ kPa ○ mmHg Choose unit first [info]
D3a	SaO$_2$ in the ABG with the **lowest** PaO$_2$ from 06:00h to 12:35h	(%) [info]
D3b	FiO$_2$ at the time of the ABG with the **lowest** PaO$_2$ from 06:00h to 12:35h	[info]

18:00h to 12:35h

D4	Highest PaO_2 from 18:00h to 12:35h?	○ kPa ○ mmHg	*Choose unit first* ☐ Not Available [info]
D4a	SaO_2 in the ABG with the **highest** PaO_2 from 18:00h to 12:35h		(%) [info]
D4b	FiO_2 at the time of the ABG with the **highest** PaO_2 from 18:00h to 12:35h		[info]
D5	Lowest PaO_2 from 18:00h to 12:35h?	○ kPa ○ mmHg	*Choose unit first* [info]
D5a	SaO_2 in the ABG with the **lowest** PaO_2 from 18:00h to 12:35h		(%) [info]
D5b	FiO_2 at the time of the ABG with the **lowest** PaO_2 from 18:00h to 12:35h		[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_2O) ☐ Not Available [info]
D7a3	P_{peak} at 08:00h?	(cmH_2O) [info]
D7a4	EPAP or CPAP pressure at 08:00h?	(cmH_2O) [info]

Remaining organ systems

D8	Highest p-lactate on this day?	(mmol/L) ☐ Not Available [info]
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]	

Consent form version 1.0

Title: Consent form

Instructions:

CONSENT FORM

Support: mail or +45 2118 2543

Co-enrollment

C0	Co-enrollment	

Upload consent form

Trial Guardian 1

C1a	Oral and written trial information given to Trial guardian 1	☐ Oral and written trial information given
C1b	Trial guardian 1 consent form	[_____] Click to upload file
C1c	Optional comment	

Trial Guardian 2

C2a	Oral and written trial information given to Trial guardian 2	☐ Oral and written trial information given
C2a1	Date when information was first given	[_____] 📅
C2b	Trial guardian 2 consent form	[_____] Click to upload file
C2c	Optional comment	

Next of Kin

C3a	Oral and written trial information given to Next of kin	☐ Oral and written trial information given
C3a1	Date when information was first given	[_____] 📅

C3b	Next of kin consent form		Click to upload file

C3c	Optional comment	

Patient

C4a	Oral and written trial information given to Patient	☐ Oral and written trial information given

C4a1	Date when information was first given		📅

C4b	Patient consent form		Click to upload file

C4c	Optional comment	

C5	All relevant consent forms collected	☐ All relevant consent forms collected [info]

Other comments

C6	Other Optional comments	

90 days follow-up form version 1.0

Title: 90 days follow-up

Instructions:

Exit (no save)

90 DAYS FOLLOW-UP

Support: mail or +45 2118 2543

F0	Date of follow-up	13-06-2020

Status at 90 days follow-up

F1	Discharged from hospital within 90 days?	◉ Yes [info] ○ No
F1a	Date of discharge from hospital?	06-06-2020 🖩 (dd-mm-yyyy)
F1b	Readmitted to hospital within 90 days?	◉ Yes [info] ○ No
F1b1	Days in hospital during readmission(s)?	6 (days) [info]
F2	Did the patient die within 90 days of follow-up?	○ Yes [info] ◉ No

Days with life support

F3	Circulatory support (infusion of vasopressor/inotropes) in **an ICU not participating in HOT-COVID?**	◉ Yes [info] ○ No

"Add" new row for each episode.

Within 90 days from randomisation.
If treatment interval exceeds 90-days follow-up date enter the date of 90-days follow-up.

F3a Start date	F3b End date	
07-06-2020 🖩 (dd-mm-yyyy)	13-06-2020 🖩 (dd-mm-yyyy)	

Add

F4	Respiratory support in **an ICU not participating in HOT-COVID?**	◉ Yes [info] ○ No

Within 90 days from randomisation.
If treatment interval exceeds 90-days follow-up date enter the date of 90-days follow-up.

F4a Start date	F4b End date	
01-06-2020 🔲 (dd-mm-yyyy)	01-06-2020 🔲 (dd-mm-yyyy)	
04-06-2020 🔲 (dd-mm-yyyy)	13-06-2020 🔲 (dd-mm-yyyy)	

[Add]

F5	Use of ECMO in **an ICU not participating in HOT-COVID?**	○ Yes [info] ⦿ No
F6	Renal replacement therapy in **an ICU not participating in HOT-COVID?**	○ Yes [info] ⦿ No

Renal replacement therapy

F7	Renal replacement therapy **outside the ICU** in the 90 days of follow-up?	⦿ Yes [info] ○ No
F7a	Date of last renal replacement therapy **outside the ICU** in the 90 days of follow-up?	🔲 (dd-mm-yyyy) [info]
F7a1	Renal replacement therapy ongoing at 90 days follow-up	☑ Yes

Return to top   [Update record]   [Exit (no save)] 🗒

1 year follow-up form version 1.0

Title: 1 year follow-up

Instructions:

Exit (no save)

1 YEAR FOLLOW-UP

F8	Date of follow-up	

Mortality

F9	Was the patient dead at one-year follow-up?	○ Yes [info] ◉ No
F9a	Date of death?	_____ 🗓 (dd-mm-yyyy)

EuroQol

F10	Lost to EuroQol follow-up?	○ Yes [info] ◉ No
F11	Date of EQ-5D-5L and EQ-vas interviews	_____ 🗓

F12 — 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

F13 — 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

F14 — 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

F15	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	
F16	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	
F17	EQ-VAS score (1-100)?		[info]
F18	EuroQol follow-up conducted by proxy?	○ Yes [info]	
		○ No	

Return to top   Exit (no save)

Discharge form version 1.0

Title: Discharge and readmission

Instructions:

DISCHARGE AND READMISSION FORM

Support: mail or +45 2118 2543

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-COVID trial ○ ICU not participating in HOT-COVID trial ○ Home (including nursing homes and similar) ○ Dead	○ Yes ○ No		X

Add

Withdrawal form version 1.0

Title: Withdrawal

Instructions:

WITHDRAWAL FORM

Support: mail or +45 2118 2543

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 [info] ○ No