

# Screening form version 1.0 – Swiss version

Screeni...(0/26)

Title: Screening

Exit (no save)

**SCREENING FORM**

Support: [mail](#) or +45 2118 2543

**Patient Identification**

S1 National identification number  [\[info\]](#)

Year of birth (yyyy)  Site ID  Serial

**Inclusion criteria**

S2 Acutely admitted to the ICU?  Yes  No [\[info\]](#)

S3 Age  $\geq$  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?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
S12	Solid organ transplant planned or conducted during current hospitalisation?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
S13	Withdrawal from active therapy or brain death deemed imminent?	<input type="radio"/> Yes <input type="radio"/> No	
S14	Known pregnancy?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
S15	Poisoned with carbon monoxide, cyanide or paraquat?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
S16	Methaemoglobinaemia?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
S17	Sickle cell disease?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
S18	Condition expected to involve the use of hyperbaric oxygen treatment (HBO)?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
S19	Consent according to national regulations NOT obtainable?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>

**Form is incomplete**

**Stratification and randomisation**

S20	Name of the patient	<input type="text"/>	<a href="#">[info]</a>
S21	Site ID	<input type="text" value="CH01"/>	
<input type="button" value="Perform randomisation"/>			
R1	Participant randomised to	<input type="text"/>	
R2	Randomisation timestamp	<input type="text"/>	

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# Baseline form version 1.0

<b>Baseline</b> (0/50)	
<b>Title:</b> Baseline	
Instructions:	
<b>BASELINE FORM</b>	
Support: <a href="#">mail</a> or +45 2118 2543	
<b>General patient information</b>	
<b>Randomisation timestamp: 15-03-2020 12:44:24</b>	
B1	Sex? <input type="radio"/> Male <input type="radio"/> Female <a href="#">[info]</a>
B2	Hospital admission date? <input type="text"/> <a href="#">(dd-mm-yyyy) [info]</a>
B3	ICU admission date? <input type="text"/> <a href="#">(dd-mm-yyyy) [info]</a>
B4	ICU admission time? <input type="text"/> <a href="#">(hh:mm, 24 hours format) [info]</a>
B5	ICU admission was directly from the operating or recovery room after surgery? <input type="radio"/> Yes <input type="radio"/> No
B5a	Type of surgery leading to ICU admission? <input type="radio"/> Elective <input type="radio"/> Acute <a href="#">[info]</a>
B6	Patient height? <input type="radio"/> cm <input type="radio"/> feet / inches <input type="text"/> (cm) <input type="text"/> (feet) <input type="text"/> (inches) <a href="#">[info]</a> <i>Choose unit first</i>
<b>Oxygen supplementation</b>	
B7	Type of oxygen supplementation system at randomisation? <input type="radio"/> Closed system <a href="#">[info]</a> <input type="radio"/> Open system
<i>Respiratory Support</i>	
B7a	Type of closed respiratory support system at randomisation? <input type="radio"/> Invasive MV <input type="radio"/> NIV or CPAP <a href="#">[info]</a>
B7a1	TV at randomisation? <input type="text"/> (mL) <a href="#">[info]</a>
B7a2	PEEP at randomisation? <input type="text"/> (cmH <sub>2</sub> O) <input type="checkbox"/> Not Available <a href="#">[info]</a>
B7a3	P <sub>peak</sub> at randomisation? <input type="text"/> (cmH <sub>2</sub> O) <a href="#">[info]</a>
B7a4	EPAP or CPAP pressure at randomisation? <input type="text"/> (cmH <sub>2</sub> O) <a href="#">[info]</a>

### Arterial Blood Gas before randomisation

- B8 PaO<sub>2</sub> in the last ABG before randomisation?  kPa  mmHg   Not Available [\[info\]](#)
- B9 SaO<sub>2</sub> 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<sub>2</sub> 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?  [\[info\]](#)  Estimated  
*If sedated, estimate the last score before sedation. If unknown write 15*
- 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?	<input type="text"/>	( $\mu\text{mol/L}$ )	<input type="checkbox"/> Not Available <a href="#">[info]</a>
B24	Lowest concentration of platelets in 24 hours prior to randomisation?	<input type="text"/>	( $\times 10^9/\text{L}$ )	<input type="checkbox"/> Not Available <a href="#">[info]</a>
B25	Urinary output in the 24 hours prior to randomisation? <i>If urine volume is measured for a short period MULTIPLY TO GET TOTAL OUTPUT IN 24 hours!</i>	<input type="text"/>	(mL) <a href="#">[info]</a>	<input type="radio"/> Estimated < 200 mL <input type="radio"/> Estimated 200-500 mL <input type="radio"/> Estimated > 500 mL
B26	Highest creatinine in the 24 hours prior to randomisation?	<input type="text"/>	( $\mu\text{mol/L}$ )	<input type="checkbox"/> Not Available <a href="#">[info]</a>

### Chronic Co-morbidities

B27	History of ischaemic heart disease?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>
B28	Chronic heart failure?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>
B29	Active metastatic cancer?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>
B30	Chronic dialysis?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>
B30a	Habitual creatinine level > 110 $\mu\text{mol/L}$ ?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a> <input type="checkbox"/> Estimated
B31	Chronic obstructive pulmonary disease (COPD)?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>
B32	Active haematological malignancy?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>

# Day form version 1.0

<b>Day form (0/42)</b>			
<b>Title: Day form</b>			
Instructions:			
<b>DAY FORM</b>			
<b>Support: mail or +45 2118 2543</b>			
Site ID	<input type="text" value="DK01"/>		
Day start date:	<input type="text" value="18-03-2020"/>	Day start time:	<input type="text" value="06:00"/>
Day end date:	<input type="text" value="18-03-2020"/>	Day end time:	<input type="text" value="12:35"/>
<b>Respiration</b>			
D1	Respiratory support on this day?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
D1a	Use of mechanical ventilation in <b>prone position</b> in the ICU on this day?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
D1b	Use of <b>inhaled vasodilators</b> during mechanical ventilation on this day?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
D1c	Use of <b>ECMO</b> in the ICU on this day?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">[info]</a>
<b>06:00h to 12:35h</b>			
D2	Highest PaO <sub>2</sub> from 06:00h to 12:35h?	<input type="radio"/> kPa <input type="radio"/> mmHg	<input type="text" value="Choose unit first"/> <input type="checkbox"/> Not Available <a href="#">[info]</a>
D2a	SaO <sub>2</sub> in the ABG with the <b>highest</b> PaO <sub>2</sub> from 06:00h to 12:35h	<input type="text"/>	(%) <a href="#">[info]</a>
D2b	FiO <sub>2</sub> at the time of the ABG with the <b>highest</b> PaO <sub>2</sub> from 06:00h to 12:35h	<input type="text"/>	<a href="#">[info]</a>
D3	Lowest PaO <sub>2</sub> from 06:00h to 12:35h?	<input type="radio"/> kPa <input type="radio"/> mmHg	<input type="text" value="Choose unit first"/> <a href="#">[info]</a>
D3a	SaO <sub>2</sub> in the ABG with the <b>lowest</b> PaO <sub>2</sub> from 06:00h to 12:35h	<input type="text"/>	(%) <a href="#">[info]</a>
D3b	FiO <sub>2</sub> at the time of the ABG with the <b>lowest</b> PaO <sub>2</sub> from 06:00h to 12:35h	<input type="text"/>	<a href="#">[info]</a>

### 18:00h to 12:35h

- D4 Highest PaO<sub>2</sub> from 18:00h to 12:35h?  kPa  mmHg   Not Available [\[info\]](#)
- D4a SaO<sub>2</sub> in the ABG with the **highest** PaO<sub>2</sub> from 18:00h to 12:35h  (%) [\[info\]](#)
- D4b FiO<sub>2</sub> at the time of the ABG with the **highest** PaO<sub>2</sub> from 18:00h to 12:35h  [\[info\]](#)
- D5 Lowest PaO<sub>2</sub> from 18:00h to 12:35h?  kPa  mmHg  [\[info\]](#)
- D5a SaO<sub>2</sub> in the ABG with the **lowest** PaO<sub>2</sub> from 18:00h to 12:35h  (%) [\[info\]](#)
- D5b FiO<sub>2</sub> at the time of the ABG with the **lowest** PaO<sub>2</sub> 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<sub>2</sub>O)  Not Available [\[info\]](#)
- D7a3 P<sub>peak</sub> at 08:00h?  (cmH<sub>2</sub>O) [\[info\]](#)
- D7a4 EPAP or CPAP pressure at 08:00h?  (cmH<sub>2</sub>O) [\[info\]](#)



### 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?	<input type="radio"/> Yes, related <input type="radio"/> Possibly related <input type="radio"/> No, not related
D12	Cerebral CT or MR scan on this day with signs of <b>new</b> ischaemic stroke?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>
D12a	Was this ischaemic stroke related to the allocated oxygenation target?	<input type="radio"/> Yes, related <input type="radio"/> Possibly related <input type="radio"/> No, not related
D13	New intestinal ischaemia on this day?	<input type="radio"/> Yes <input type="radio"/> No <a href="#">[info]</a>
D13a	Was this intestinal ischaemia related to the allocated oxygenation target?	<input type="radio"/> Yes, related <input type="radio"/> Possibly related <input type="radio"/> No, not related
D14	Number of units of red blood cells transfused on this day?	<input type="text"/> (Units) <a href="#">[info]</a>



# Consent form version 1.0

<b>Consent...(0/18)</b>	
<b>Title: Consent form</b>	
Instructions:	
<b>CONSENT FORM</b>	
Support: mail or +45 2118 2543	
<b>Co-enrollment</b>	
C0	Co-enrollment <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<b>Upload consent form</b>	
<i>Trial Guardian 1</i>	
C1a	Oral and written trial information given to Trial guardian 1 <input type="checkbox"/> Oral and written trial information given
C1b	Trial guardian 1 consent form <input type="text"/> <a href="#">Click to upload file</a>
C1c	Optional comment <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<i>Trial Guardian 2</i>	
C2a	Oral and written trial information given to Trial guardian 2 <input type="checkbox"/> Oral and written trial information given
C2a1	Date when information was first given <input type="text"/> 
C2b	Trial guardian 2 consent form <input type="text"/> <a href="#">Click to upload file</a>
C2c	Optional comment <div style="border: 1px solid gray; height: 60px; width: 100%;"></div>
<i>Next of Kin</i>	
C3a	Oral and written trial information given to Next of kin <input type="checkbox"/> Oral and written trial information given
C3a1	Date when information was first given <input type="text"/> 

C3b	Next of kin consent form	<input type="text"/>	<input type="button" value="Click to upload file"/>
C3c	Optional comment	<input type="text"/>	
<b>Patient</b>			
C4a	Oral and written trial information given to Patient	<input type="checkbox"/> Oral and written trial information given	
C4a1	Date when information was first given	<input type="text"/>	<input type="button" value="Calendar"/>
C4b	Patient consent form	<input type="text"/>	<input type="button" value="Click to upload file"/>
C4c	Optional comment	<input type="text"/>	
C5	All relevant consent forms collected	<input type="checkbox"/> All relevant consent forms collected <a href="#">[info]</a>	
<b>Other comments</b>			
C6	Other Optional comments	<input type="text"/>	

# 90 days follow-up form version 1.0

**undefined**

**Title: 90 days follow-up**

Instructions:

[Exit \(no save\)](#)

**90 DAYS FOLLOW-UP**

Support: [mail](#) or +45 2118 2543

F0 Date of follow-up

**Status at 90 days follow-up**

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 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
<input type="text" value="07-06-2020"/> <input type="button" value="📅"/> (dd-mm-yyyy)	<input type="text" value="13-06-2020"/> <input type="button" value="📅"/> (dd-mm-yyyy)
<a href="#">Add</a>	

F4 Respiratory support 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.**

F4a Start date	F4b End date	
<input type="text" value="01-06-2020"/>  (dd-mm-yyyy)	<input type="text" value="01-06-2020"/>  (dd-mm-yyyy)	
<input type="text" value="04-06-2020"/>  (dd-mm-yyyy)	<input type="text" value="13-06-2020"/>  (dd-mm-yyyy)	
<input type="button" value="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

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# 1 year follow-up form version 1.0

<b>undefined</b>	
<b>Title: 1 year follow-up</b>	
Instructions:	
<a href="#">Exit (no save)</a>	
<b>1 YEAR FOLLOW-UP</b>	
F8	Date of follow-up <input type="text"/>
<b>Mortality</b>	
F9	Was the patient dead at one-year follow-up? <input type="radio"/> Yes <a href="#">[info]</a> <input checked="" type="radio"/> No
F9a	Date of death? <input type="text"/> <input type="button" value="📅"/> (dd-mm-yyyy)
<b>EuroQol</b>	
F10	Lost to EuroQol follow-up? <input type="radio"/> Yes <a href="#">[info]</a> <input checked="" type="radio"/> No
F11	Date of EQ-5D-5L and EQ-vas interviews <input type="text"/> <input type="button" value="📅"/>
F12	EQ-5D-5L score <b>Mobility</b> ? <input type="radio"/> I have no problems in walking about <a href="#">[info]</a> <input type="radio"/> I have slight problems in walking about <input type="radio"/> I have moderate problems in walking about <input type="radio"/> I have severe problems in walking about <input type="radio"/> I am unable to walk about <input type="radio"/> The answer is not obtainable
F13	EQ-5D-5L score <b>Self-care</b> ? <input type="radio"/> I have no problems with washing or dressing myself <a href="#">[info]</a> <input type="radio"/> I have slight problems with washing or dressing myself <input type="radio"/> I have moderate problems with washing or dressing myself <input type="radio"/> I have severe problems with washing or dressing myself <input type="radio"/> I am unable to wash or dress myself <input type="radio"/> The answer is not obtainable
F14	EQ-5D-5L score <b>Usual activities</b> ? <input type="radio"/> I have no problems doing my usual activities <a href="#">[info]</a> <input type="radio"/> I have slight problems doing my usual activities <input type="radio"/> I have moderate problems doing my usual activities <input type="radio"/> I have severe problems doing my usual activities <input type="radio"/> I am unable to do my usual activities <input type="radio"/> The answer is not obtainable

F15 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 discomfort
- The answer is not obtainable

F16 EQ-5D-5L score **Anxiety/depression?** [\[info\]](#)

- I am not anxious or depressed
- I am slightly 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? [\[info\]](#)

- Yes
- No

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[Exit \(no save\)](#)



# Discharge form version 1.0

Dischar... (0/7)

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 <a href="#">[info]</a>	Has the patient been enrolled in other interventional trials during this ICU admission	Patient transferred to site Id
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> General Ward <input type="radio"/> ICU participating in HOT-COVID trial <input type="radio"/> ICU not participating in HOT-COVID trial <input type="radio"/> Home (including nursing homes and similar) <input type="radio"/> Dead	<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/>

[Add](#)

# Withdrawal form version 1.0

<b>Withdra...(0/5)</b>	
<b>Title: Withdrawal</b>	
Instructions:	
<b>WITHDRAWAL FORM</b>	
Support: <a href="#">mail</a> or +45 2118 2543	
<b>Withdrawal from intervention and/or data registration</b>	
W1	Date of withdrawal? <input type="text"/>  (dd-mm-yyyy)
W2	Time of withdrawal? (24 hours) <input type="text"/> (hh:mm)
W3	Reason for withdrawal? <input type="radio"/> SUSAR <a href="#">[info]</a> <input type="radio"/> Consent not given or withdrawn
W3a	Who is not giving or withdrawing consent? <input type="radio"/> Relative/next of kin/guardian not giving or withdrawing consent <input type="radio"/> Patient not giving or withdrawing consent
W3b	Will further daily data be registered? <input type="radio"/> Yes <a href="#">[info]</a> <input type="radio"/> No