

## Screening v. 1.1 (Switzerland)

Screeni...(0/28)

Title: Screening

Instructions:

### SCREENING FORM

#### 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** with an  $\text{FiO}_2 \geq 0.50$ ?  Yes  No [\[info\]](#)

S5 Oxygen supplementation through an **open system** with a oxygen flow of  $\geq 10$  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 Initials of the patient  [\[info\]](#)  Unknown at admission

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?  [\[calendar\]](#) (dd-mm-yyyy) [\[info\]](#)

B3 ICU admission date?  [\[calendar\]](#) (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<sub>2</sub>O) [\[info\]](#)  Not Available

B7c P<sub>peak</sub> at randomisation?  (cmH<sub>2</sub>O) [\[info\]](#)

B7d EPAP or CPAP pressure at randomisation?  (cmH<sub>2</sub>O) [\[info\]](#)

**Arterial Blood Gas before randomisation**

B8 PaO<sub>2</sub> in the last ABG before randomisation?  kPa  mmHg  *Choose unit first* [\[info\]](#)  Not Available

B9 SaO<sub>2</sub> 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<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 [\[info\]](#)

B22a Highest dose of dopamine in the 24 hours prior to randomisation?  ( $\mu\text{g}/\text{kg}/\text{min}$ ) [\[info\]](#)

*If dopamine has not been used write 0*

B22b Highest dose of norepinephrine (noradrenalin) in the 24 hours prior to randomisation?  ( $\mu\text{g}/\text{kg}/\text{min}$ ) [\[info\]](#)

*If norepinephrine has not been used write 0*

B22c Highest dose of epinephrine (adrenalin) in the 24 hours prior to randomisation?  ( $\mu\text{g}/\text{kg}/\text{min}$ ) [\[info\]](#)

*If epinephrine has not been used write 0*

B23 Highest concentration of bilirubin in 24 hours prior to randomisation?  ( $\mu\text{mol}/\text{L}$ ) [\[info\]](#)  Not Available

B24 Lowest concentration of platelets in 24 hours prior to randomisation?  ( $\times 10^9/\text{L}$ ) [\[info\]](#)  Not Available

B25 Urinary output in the 24 hours prior to randomisation?  (mL) [\[info\]](#)  Estimated < 200 ml

*If urine volume is measured for a short period MULTIPLY TO GET TOTAL OUTPUT IN 24 hours!*

Estimated 200-500 ml  
 Estimated > 500 ml

B26 Highest creatinine in the 24 hours prior to randomisation?  ( $\mu\text{mol}/\text{L}$ ) [\[info\]](#)  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  $\mu\text{mol}/\text{L}$ ?  Yes  No [\[info\]](#)  Estimated

Daily F...(0/42)

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<sub>2</sub> from 06:00h to 18:00h?  kPa  mmHg  [\[info\]](#)  Not Available
- D2a SaO<sub>2</sub> in the ABG with the **highest** PaO<sub>2</sub> from 06:00h to 18:00h  (%) [\[info\]](#)
- D2b FIO<sub>2</sub> at the time of the ABG with the **highest** PaO<sub>2</sub> from 06:00h to 18:00h  [\[info\]](#)
- D3 Lowest PaO<sub>2</sub> from 06:00h to 18:00h?  kPa  mmHg  [\[info\]](#)
- D3a SaO<sub>2</sub> in the ABG with the **lowest** PaO<sub>2</sub> from 06:00h to 18:00h  (%) [\[info\]](#)
- D3b FIO<sub>2</sub> at the time of the ABG with the **lowest** PaO<sub>2</sub> from 06:00h to 18:00h  [\[info\]](#)

**18:00h to 06:00h**

- D4 Highest PaO<sub>2</sub> from 18:00h to 06:00h?  kPa  mmHg  [\[info\]](#)  Not Available
- D4a SaO<sub>2</sub> in the ABG with the **highest** PaO<sub>2</sub> from 18:00h to 06:00h  (%) [\[info\]](#)
- D4b FIO<sub>2</sub> at the time of the ABG with the **highest** PaO<sub>2</sub> from 18:00h to 06:00h  [\[info\]](#)
- D5 Lowest PaO<sub>2</sub> from 18:00h to 06:00h?  kPa  mmHg  [\[info\]](#)
- D5a SaO<sub>2</sub> in the ABG with the **lowest** PaO<sub>2</sub> from 18:00h to 06:00h  (%) [\[info\]](#)
- D5b FIO<sub>2</sub> at the time of the ABG with the **lowest** PaO<sub>2</sub> from 18:00h to 06:00h  [\[info\]](#)

## 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]

D7a1TV at 08:00h?  (mL) [info]

D7a2PEEP at 08:00h?  (cmH<sub>2</sub>O) [info]  Not Available

D7a3P<sub>peak</sub> at 08:00h?  (cmH<sub>2</sub>O) [info]

D7a4EPAP or CPAP pressure at 08:00h?  (cmH<sub>2</sub>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]

D11aWas 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]

D12aWas 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]

D13aWas 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]

<b>Withdra...(5/5)</b>	
<b>Title: Withdrawal</b>	
Instructions:	
<b>WITHDRAWAL FORM</b>	
<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 <input type="radio"/> 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 <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="radio"/> General Ward <input type="radio"/> ICU participating in HOT-ICU trial <input type="radio"/> ICU not participating in HOT-ICU 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"/>
<input type="text"/>	<input type="text"/>					<input type="text"/>



## Follow-Up 90 days version 1.0

Follow-...(6/10)

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

F1b1Days 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

<b>Follow-...(0/13)</b>	
<b>Title: Follow-up 1 year</b>	
Instructions:	
<b>1 YEAR FOLLOW-UP</b>	
F4 Date of follow-up	<input type="text"/> Calculated as 365 days after randomisation
<b>Mortality</b>	
F5 Was the patient dead at one-year follow-up?	<input type="radio"/> Yes <a href="#">[info]</a> <input type="radio"/> No
<b>EuroQol</b>	
F6 Lost to EuroQol follow-up?	<input type="radio"/> Yes <a href="#">[info]</a> <input type="radio"/> No
F6a Reason for lost to EuroQol follow-up	<input type="radio"/> Unable to get hold of the patient <input type="radio"/> Patient did not wish to participate <input type="radio"/> Other
F6b Please specify other reason	<input type="text"/>
F7 Date of EQ-5D-5L and EQ-vas interviews	<input type="text"/> 
F8 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
F9 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
F10 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
F11 EQ-5D-5L score <b>Pain/discomfort?</b>	<input type="radio"/> I have no pain or discomfort <a href="#">[info]</a> <input type="radio"/> I have slight pain or discomfort <input type="radio"/> I have moderate pain or discomfort <input type="radio"/> I have severe pain or discomfort <input type="radio"/> I have extreme pain or discomfort <input type="radio"/> The answer is not obtainable
F12 EQ-5D-5L score <b>Anxiety/depression?</b>	<input type="radio"/> I am not anxious or depressed <a href="#">[info]</a> <input type="radio"/> I am slightly anxious or depressed <input type="radio"/> I am moderately anxious or depressed <input type="radio"/> I am severely anxious or depressed <input type="radio"/> I am extremely anxious or depressed <input type="radio"/> The answer is not obtainable
F13 EQ-VAS score (1-100)?	<input type="text"/> <a href="#">[info]</a>
F14 EuroQol follow-up conducted by proxy?	<input type="radio"/> Yes <a href="#">[info]</a> <input type="radio"/> No