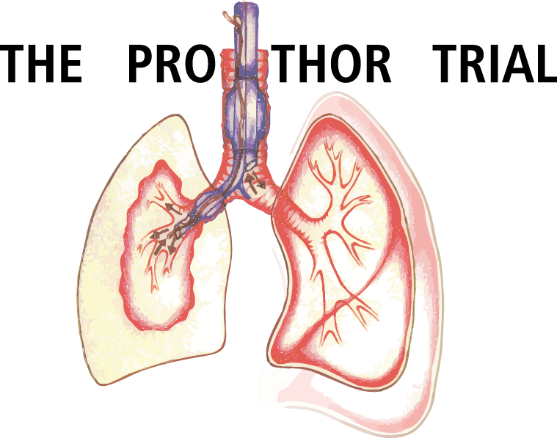
**CONFIDENTIAL**



**POSTOPERATIVE ASSESSMENT**

**Discharge and Followup**

**Case Report Form**

**version 1.8**

Protective Ventilation with Higher versus Lower PEEP during one-lung ventilation for thoracic surgery

**Patient Serial Number** |\_\_|\_\_|\_\_**|**\_\_|\_\_|\_\_|

c e n t e r p a t i e n t

**Date of assessment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Local investigator 1 (intraoperative) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Local investigator 2 (postoperative) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**DISCHARGE**

**(report events within last visit to discharge from hospital)**

# 1 Discharge

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date of discharge | yes 🞎 no 🞎 | if yes | reason |  |
| Discharge destination: Home 🞎 Other hospital/rehabilitation 🞎Death 🞎  other🞎 please specify: | | | | |
| Patient alive at time of discharge? Yes🞎 no🞎 | | | | |

# 2 Recovery

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Visit date: | | |  | |  | | | |  | | |  |
| Lost to follow up or discharge | | | yes 🞎 no 🞎 | | |  | | |  | | |  |
| Reason | | | discharged 🞎 consent withdrawal 🞎 | | | |  | | death 🞎: | |  | |
| other 🞎, specify: | |  | |
| New requirement of NIV | | yes 🞎 no 🞎 | | | if yes | | | CPAP 🞎 NPPV 🞎  other 🞎specify: | | | | duration [hrs] |
|  | |  | | |  | | | maximum intensity [pressure level]: | | | | |
|  | |  | | | indication | | | standard of care 🞎 resp. failure 🞎  other 🞎, specify: | | | | |
| New requirement of invasive MV | | yes 🞎 no 🞎 | | | if yes | | | duration [hrs] | | | |  |
|  | |  | | | indication | | | re-surgery 🞎 resp. failure 🞎 other 🞎 , specify: | | | | |
| unplanned ICU admission | | yes 🞎 no 🞎 | | | if yes | | | indication: | | | | |
| Cumulated Ambulation Score [0-6]: | | | | | | | | | | | | |
| Impairment of wound healing | | yes 🞎 no 🞎 | | | if yes | | | superficial 🞎 deep 🞎 | | | | |
| Surgical wound infection | | yes 🞎 no  🞎 | | | if yes | | | superficial 🞎 deep 🞎 | | | | |
|  | |  | | | if yes | | | abscess 🞎 empyema 🞎 phlegmon 🞎 | | | | |
| Antibiotics | yes 🞎 no 🞎 | | | if yes, specify drug name: | | | | | | prophylaxis 🞎 therapy 🞎 | | |

# 2 Actual organ function

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SpO2 supine position, upper body elevated 30-45°, 10 min in room air possible? | yes 🞎 no 🞎 | | if yes | | | | SpO2 [%]: | | | |
|  |  | | if no | | | | SpO2 [%]: | | **and** FiO2 [%]: |
| RR [/min] | | | | | | | | | | |
| HR [/min] | | | | | ABP mean [mmHg] | | | | | |
| Temperature [°C] | | | | tympanic 🞎 axillar 🞎 inguinal 🞎 oral 🞎 rectal 🞎 | | | | | | |
|  | | | | other 🞎 | | | | if other specify: | | |
| Airway secretion | yes 🞎 no 🞎 | if yes | | | | purulent/yellow colour 🞎 not purulent 🞎 | | | | |
| VAS dyspnea [1-10cm] | | | | | VAS thoracic rest pain [1-10cm] | | | | | |
|  | | | | | VAS coughing pain [1-10cm] | | | | | |

# 3 Non-mandatory measurements

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Laboratory tests** |  |  |
| **Chest X-ray** obtained | yes 🞎 no 🞎 | Hb | mmol/l 🞎 | g/dl 🞎 |
| if yes |  | Hematocrit | % |  |
| Infiltrates (any side) | yes 🞎 no 🞎 | WBC | GPt/L |  |
| pleural effusion (any side) | yes 🞎 no 🞎 | Platelets | GPt/L |  |
|  |  | INR |  |  |
| Atelectasis (any side) | yes 🞎 no 🞎 | PTT | sec |  |
| Pneumothorax (any side) | yes 🞎 no 🞎 | Creatinine | µmol/l 🞎 | mg/dl 🞎 |
| cardiopulmonary edema  (any side) | yes 🞎 no 🞎 | BUN | mmol/l 🞎 | mg/dl 🞎 |
|  |  | ALT | µmol/s\*l 🞎 | U/L 🞎 |
|  |  | AST | µmol/s\*l 🞎 | U/L 🞎 |
|  |  | Bilirubin | µmol/l 🞎 | mg/dl 🞎 |
|  |  | CRP c-reactive protein | mg/l |  |
|  |  | Procalcitonin | ng/ml |  |

# 4 Pulmonary complications

|  |  |  |
| --- | --- | --- |
| Aspiration pneumonitis  resp. failure after inhalation of gastric contents  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Severe respiratory failure  need for non-invasive or invasive mechanical ventilation due to poor oxygenation | | yes 🞎 no 🞎 |
| Moderate respiratory failure  SpO2<90% or PaO2<60mmHg for 10min in room air, responding to oxygen > 2l/min | | yes 🞎 no 🞎 |
| ARDS according to Berlin definition | yes 🞎 no 🞎 | if yes |
| mild🞎 moderate🞎 severe🞎 |
| Pulmonary infection  new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Atelectasis  lung opacification with shift of surrounding tissue/ organ towards the affected area  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Cardiopulmonary edema  clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray, not explained by poor cardiac function  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Pleural effusion  blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray, not explained by the preoperative patient condition alone  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Pneumothorax  free air in the pleural space on chest X-ray/ ultrasonic imaging  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎  for this study, pneumothorax at the operated side will not be considered as a PPC; please mark anyway | | yes 🞎 no 🞎 |
| Pulmonary infiltrates  monolateral/ bilateral infiltrates without other clinical signs  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Prolonged air leakage  Air leak requiring at least 7 days of postoperative chest tube drainage  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Purulent pleuritis Receiving antibiotics for a suspected infection, as far as not explained by the preoperative patient condition alone  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Pulmonary Embolism As documented by pulmonary arteriogram or autopsy, or supported by a ventilation/perfusion radioisotope scans, or documented by echocardiography and receiving specific therapy  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |
| Lung haemorrhage Bleeding through the chest tubes requiring reoperation, or three or more red blood cell packs  left 🞎 right 🞎 both🞎 cannot be differentiated 🞎 | | yes 🞎 no 🞎 |

**Extended PPCs:**

|  |  |
| --- | --- |
| Bronchospasm  newly expiratory wheezing treated with bronchodilators | yes 🞎 no 🞎 |
| Mild respiratory failure  SpO2<90% or PaO2<60mmHg for 10min in room air, responding to oxygen ≤ 2l/min | yes 🞎 no 🞎 |

# 5 Extrapulmonary complications

|  |  |  |  |
| --- | --- | --- | --- |
| SIRS  ≥2 findings: Temp < 36 0C or > 38 0C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl | | | yes 🞎 no 🞎 |
| Sepsis  SIRS in response to a confirmed infective process | | | yes 🞎 no 🞎 |
| Severe Sepsis  Sepsis with organ dysfunction, hypoperfusion or hypotension | | | yes 🞎 no 🞎 |
| Septic shock  Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation | | | yes 🞎 no 🞎 |
| Extrapulmonary infection  wound infection + any other (extrapulmonary) infection | | | yes 🞎 no 🞎 |
| Coma  Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives | | | yes 🞎 no 🞎 |
| Acute myocardial infarction  rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death | | | yes 🞎 no 🞎 |
| Acute renal failure  **R**isk: Crea increased 1.5 times baseline or GFR decrease > 25% *or* urine output < 0.5 ml/kg/h within 6 hr  **I**njury: Crea increased 2 times baseline or GFR decrease > 50% *or* urine output < 0.5 ml/kg/h within 12 hr  **F**ailure: Crea increase 3 times baseline or GFR decrease > 75% *or* urine output < 0.3 ml/kg/h within 24 hr or anuria for 12 hrs  **L**oss: complete loss of kidney function > 4 weeks(requiring dialysis) | | | |
| yes 🞎 no 🞎 | if yes | R 🞎 I 🞎 F 🞎 L 🞎 | |
| Disseminated intravascular coagulation  according to DIC score > 5 | | | yes 🞎 no 🞎 |
| Stroke  New clinical signs of stroke lasting > 24h + corresponding findings in radiologic imaging | | | yes 🞎 no 🞎 |
| Hepatic failure  bilirubin > 2 mg/dL + elevation of ALT/AST + LDH x2 above normal values ALT/AST + LDH x2 above normal values | | | yes 🞎 no 🞎 |
| Gastrointestinal failure  1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery  2 = food intolerance (FI) *or* intra–abdominal hypertension (IAH)  3 = FI and IAH  4 = abdominal compartment syndrome (ACS) | | | yes 🞎 no 🞎 if yes  1 🞎 2 🞎 3 🞎 4 🞎  gastrointestinal bleeding 🞎 |

# 6 Adverse events (AE) / severe adverse events (SAE)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Any adverse events | yes 🞎 no 🞎 | | if yes | specify according to table: | | |
|  |  | |  |  | | |
| Event (details, including treatment) | | Severe AE | Causality | | Severity | Outcome |
|  | | yes 🞎  no 🞎 | unrelated 🞎  possible 🞎  probable 🞎  unassessable 🞎 | | mild 🞎  moderate 🞎  severe 🞎  unassessable 🞎 | resolved - no sequelae 🞎  resolved - sequelae 🞎  unresolved 🞎  death 🞎  unknown 🞎 |
|  | | yes 🞎  no 🞎 | unrelated 🞎  possible 🞎  probable 🞎  unassessable 🞎 | | mild 🞎  moderate 🞎  severe 🞎  unassessable 🞎 | resolved - no sequelae 🞎  resolved - sequelae 🞎  unresolved 🞎  death 🞎  unknown 🞎 |
|  | | yes 🞎  no 🞎 | unrelated 🞎  possible 🞎  probable 🞎  unassessable 🞎 | | mild 🞎  moderate 🞎  severe 🞎  unassessable 🞎 | resolved - no sequelae 🞎  resolved - sequelae 🞎  unresolved 🞎  death 🞎  unknown 🞎 |

**FOLLOWUP**

**(report events within DISCHARGE to DAY-28 and 90 after randomisation)**

# 7 Followup

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date of follow up: |  |  |  |  |
| Lost to follow up | yes 🞎 no 🞎 | if yes | specify: |  |
| Rehospitalisation after discharge | yes 🞎 no 🞎 |  | Hospital readmission is only counted if the patient stays overnight (= 2 days) |  |
| if yes, how many days of hospitalisation after discharge? | | |  | |
| Please enter the specific days the patient has been in hospital after discharge (e.g. from 12 May until 16 May 2016) | | |  | |
| Hospital free days at day 28  (defined as the number of days that a patient was not in hospital nor rehabilitation or nursing facility at day 28 after randomization. Hospital readmission is only counted if the patient stays overnight (= 2 days). Patients who die or have longer length of stay than 28 days are assigned zero hospital free days) | | |  | |
| Alive or dead at day 90 after study inclusion  alive🞎 dead 🞎 | | |  | |

# 8 Adverse events (AE) / severe adverse events (SAE)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Any adverse events | yes 🞎 no 🞎 | | if yes | specify according to table: | | |
|  |  | |  |  | | |
| Event (details, including treatment) | | Severe AE | Causality | | Severity | Outcome |
|  | | yes 🞎  no 🞎 | unrelated 🞎  possible 🞎  probable 🞎  unassessable 🞎 | | mild 🞎  moderate 🞎  severe 🞎  unassessable 🞎 | resolved - no sequelae 🞎  resolved - sequelae 🞎  unresolved 🞎  death 🞎  unknown 🞎 |
|  | | yes 🞎  no 🞎 | unrelated 🞎  possible 🞎  probable 🞎  unassessable 🞎 | | mild 🞎  moderate 🞎  severe 🞎  unassessable 🞎 | resolved - no sequelae 🞎  resolved - sequelae 🞎  unresolved 🞎  death 🞎  unknown 🞎 |
|  | | yes 🞎  no 🞎 | unrelated 🞎  possible 🞎  probable 🞎  unassessable 🞎 | | mild 🞎  moderate 🞎  severe 🞎  unassessable 🞎 | resolved - no sequelae 🞎  resolved - sequelae 🞎  unresolved 🞎  death 🞎  unknown 🞎 |