**Primary data source**

**Title:** The Conservative vs. Liberal Approach to fluid therapy of Septic Shock in Intensive Care (CLASSIC) Trial

**Department:**

**Hospital:**

**Investigator:**

|  |  |
| --- | --- |
| **Data** | **Primary data source** |
| Consent |  |
| **SCREENING FORM** |  |
| National identification number |  |
| **INCLUSION CRITERIA** |  |
| Age |  |
| Admission or planed admission to ICU |  |
| Septic shock according to the Sepsis-3 criteria? |  |
| At least 1 L of IV fluid in the last 24-hours prior to screening? |  |
| **EXCLUSION CRITERIA** |  |
| Has the patient had septic shock for more than 12 hours at the time of screening? |  |
| Does the patient have life-threatening bleeding? |  |
| Does the patient have acute burn injury of more than 10% of the body surface area? |  |
| Is the patient pregnant? |  |
| Consent unobtainable according to national regulations? |  |

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| **Data** | **Primary data source** |
| **STRATIFICATION VARIABLES** |  |
| Site |  |
| Metastatic cancer or hematological malignancy? |  |
| **BASELINE FORM** |  |
| **GENERAL PATIENT INFORMATION** |  |
| Sex |  |
| Date-of-birth |  |
| Hospital admission date? |  |
| ICU admission date and time? |  |
| Location before ICU admission? |  |
| Focus of infection? |  |
| **Co-morbidities** |  |
| Ischemic heart disease? |  |
| Chronic hypertension? |  |
| Chronic renal replacement therapy? |  |
| **Blood values, interventions and vital parameters** |  |
| Weight |  |
| Highest plasma lactate 3 hours prior to randomisation? |  |
| Highest dose of noradrenaline 3 hours prior to randomisation? |  |
| Infused IV fluid volume 24 hours prior to randomisation? |  |
| Use of systemic corticosteroids 24 hours prior to randomisation? |  |
| Highest plasma creatinine value 24 hours prior to randomisation? |  |
| Use of acute renal replacement therapy 3 days prior to randomisation? |  |
| Habitual plasma creatinine value prior to current hospitalisation? |  |
|  |  |
| **SMS-ICU** |  |
| Systolic blood pressure |  |
| Vasopressors |  |
| Respiratory support |  |
| Renal replacement therapy |  |
| Acute surgery |  |
| **DAY FORM** |  |
| **Time span** |  |
| Date/time |  |
| **Fluid input and output** |  |
| IV crystalloids? |  |
| IV fluid of other types? |  |
| IV albumin? |  |
| IV fluid with medication? |  |
| Enteral and parenteral nutrition? |  |
| Non-nutritional enteral/oral fluid? |  |
| Blood products? |  |
| Urinary output? |  |
| Renal replacement therapy and volume of fluid removal? |  |
| Other fluid losses? |  |
| **Major protocol violations** |  |
| Volume IV fluids given without one of the extenuating circumstances? |  |
| **Co-interventions** |  |
| Vasopressor/inotropes? |  |
| Systemic corticosteroids? |  |
| Invasive mechanical ventilation? |  |
| Renal replacement therapy? |  |
| **OUTCOMES** |  |
| Creatinine |  |
| Cerebral ischemia? |  |
| Acute myocardial ischemia? |  |
| Intestinal ischemia? |  |
| Limb ischemia? |  |
| **SAR** |  |
| Anaphylactic reaction |  |
| General tonic-clonic seizures |  |
| Central pontine myelinolysis |  |
| Hypernatremia |  |
| Severe hyperchloremic acidosis |  |
| Severe metabolic alkalosis |  |
| **DISCHARGE AND READMISSION FORM** |  |
| Date/time |  |
| Discharged to |  |
| Date/time of possible readmission |  |
| **WITHDRAWAL FORM** |  |
| Date/time |  |
| Reason |  |
| Consent not given/further data registration |  |
| **90 DAYS FOLLOW-UP** |  |
| Date |  |
| If discharged from hospital within 90 days: Date of discharge and additional admissions |  |
| Dead |  |

Investigator (navn): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dato: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_ Underskrift: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**VEJLEDNING**

**Kildedokument**

Kildedatalisten anvendes af Good Clinical Practice (GCP) monitorerne til at validere indtastede data. Kildedokumentet er det første sted data registreres. Der skal angives en kilde til samtlige data, der indsamles i CRF’en og henvisningerne skal opføres i kildedatalisten. Hvis flere kilder er mulige, skal alle angives i prioriteret rækkefølge, dvs. kilder der vægter højest hvis data i de forskellige kilder ikke er identiske placeres først.

**Eksempler på kildedokumenter, som kan være både elektroniske og fysiske dokumenter**

EKG-udskrift, elektronisk medicin-journal, eCRF, epikrise, journalkontinuationer, sygeplejenotater osv.

Beskriv kildedokumentet så specifikt som muligt.

**Udarbejdelse og opbevaring**

Kildedatalisten skal foreligge underskrevet af lokal investigator ved initieringsbesøget. Det kan være nødvendigt at revidere listen undervejs i forsøget. Alle underskrevne versioner af listen, skal arkiveres i site master file.