**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 (name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**GUIDE**

**Data source document**

The primary data source list will be used by the Good Clinical Practice (GCP) monitors to validate the data entered in the CLASSIC eCRF. A source of all data entered in the eCRF should be listed with references in the primary data source list. If several sources are present, they must be listed in prioritized order in the list.

**Development**

A data source list signed by the local investigator must be present at the GCP initiation meeting. It can be necessary to update the list during the course of the trial. All signed versions of the list must be archived in the site master file.