

Crystalloids Liberal or Vasopressors Early Resuscitation in Sepsis

Status: OPEN TO ACCRUAL

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- Age ≥ 18 years
- A suspected or confirmed infection (broadly defined by administration or planned administration of antibiotics)
- Sepsis-induced hypotension defined as systolic blood pressure < 100 mmHg or MAP < 65 mmHg after a minimum of at least 1 liter of fluid (*Fluids inclusive of pre-hospital fluids; blood pressure must be below any known or reported pre-morbid baseline).

Exclusion Criteria:

- More than 4 hours elapsed since meeting inclusion criteria or 24 hours elapsed since admission to the hospital
- Patient already received 3 liters of intravenous fluid (includes prehospital volumes)
- Unable to obtain informed consent
- Known pregnancy
- Hypotension suspected to be due to non-sepsis cause (e.g. hemorrhagic shock)
- Blood pressure is at known or reported baseline level
- Severe Volume Depletion from an acute condition other than sepsis. In the judgment of the treating physician, the patient has an acute condition other than sepsis causing (or indicative) of *severe volume depletion; Examples include: Diabetic ketoacidosis, high volume vomiting or diarrhea, hyperosmolar hyperglycemic state, and nonexertional hyperthermia (heat stroke); severe is defined by the need for substantial intravenous fluid administration as part of routine clinical care
- Pulmonary edema or clinical signs of new fluid overload (e.g. bilateral crackles, new oxygen requirement, new peripheral edema, fluid overload on chest x-ray)
- Treating physician unwilling to give additional fluids as directed by the liberal protocol
- Treating physician unwilling to use vasopressors as directed by the restrictive protocol.
- Current or imminent decision to withhold most/all life-sustaining treatment; this does not exclude those patients committed to full support except cardiopulmonary resuscitation
- Immediate surgical intervention planned such that study procedures could not be followed
- Prior enrollment in this study

Conditions & Interventions

Interventions:

Drug: Early Vasopressors, Drug: Early Fluids, drug: Ringer's (hartmann's) lactate solution, drug: Plasmalyte (crystalloid) solution, drug: Normal (0.9%, isotonic) saline solution, drug: Norepinephrine

Conditions:

Septic Shock, Symptoms, Signs, and Ill-Defined Conditions (780-799)

Keywords:

Fluid management, Sepsis-induced hypotension, vasopressors

More Information

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Phase: III

IRB

Number: HM20013528

System ID: NCT03434028

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