Pragmatic Pediatric Trial of Balanced Versus Normal Saline Fluid in Sepsis

Status: RECRUITING

Eligibility Criteria

Age: 2 months to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Males or females age \>2 months to \<18 years 2. Clinician concern for septic shock, operationalized as: 1. a "positive" ED sepsis alert confirmed by a physician OR 2. physician decision to treat for septic shock OR 3. a physician diagnosis of septic shock requiring parenteral antibiotics and fluid resuscitation 3. Administration of at least one IV/Intraosseous (IO) fluid bolus for resuscitation and additional fluid deemed likely to be necessary to treat poor perfusion, or clinician judgment that \>1 fluid bolus is highly likely to be required. Poor perfusion is defined as physician's judgement of hypotension or abnormal (either "flash" or "prolonged") capillary refill. 4. Receipt of ≤40 mL/kg IV/IO total crystalloid fluid prior to randomization 5. Parental/guardian permission (informed consent) if time permits; otherwise, Exception from informed consent (EFIC) criteria met

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Exclusion Criteria:

1. Treating physician judges that patient's condition deems it unsafe to administer either NS or BF (since patients will be equally likely to receive NS or BF at time of study enrollment), including: 1. Clinical suspicion for impending brain herniation 2. Known hyperkalemia, defined as non-hemolyzed whole blood or plasma/serum potassium \> 6 mEq/L, based on data available at or before patient meets criteria for study enrollment 3. Known hypercalcemia, defined as plasma/serum total calcium \>12 mg/dL or whole blood ionized calcium \>1.35 mmol/L, based on data available at or before patient meets criteria for study enrollment 4. Known acute fulminant hepatic failure, defined as plasma/serum alanine aminotransferase (ALT) \>10,000 U/L or total bilirubin \>12.0 mg/dL, based on data available at or before patient meets criteria for study enrollment 5. Known history of severe hepatic impairment, defined as cirrhosis, "liver failure", or awaiting transplant 6. Known history of severe renal impairment, defined as peritoneal dialysis or hemodialysis 7. Known metabolic/mitochondrial disorder, inborn error of metabolism, or primary mineralocorticoid deficiency as reported by participant, legally authorized representative (LAR) or accompanying caregiver, or as listed in the medical record 8. Other concern for which the treating clinician deems it unsafe to administer either NS or LR 2. Known pregnancy determined by routine history disclosed by patient and/or accompanying acquaintance. 3. Known prisoner 4. Known allergy to a crystalloid fluid 5. Indication of declined consent to participate based on presence of an opt-out bracelet with appropriate messaging embossed into the bracelet, the presence of the patient's name on an opt-out list that will be kept up-to-date and checked prior to randomization, or verbal "opt-out" prior to enrollment.

Conditions & Interventions

Interventions:
DRUG: Lactated Ringer, DRUG: Normal Saline, DRUG: Plasma-lyte
Conditions:
Shock, Septic
Keywords:
Sepsis, Septic Shock, Fluid resuscitation, Saline, Balanced Fluid, Mortality, Crystalloid, PlasmaLyte, Lactated Ringer's, Kidney injury

More Information

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