Stress Hydrocortisone In Pediatric Septic Shock

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 month to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

A child receiving treatment in a pediatric intensive care unit is eligible for recruitment into SHIPSS if she/he meets all of the following inclusion criteria:

1. Age is at least 1 month (with corrected gestational age ≥42 weeks), but less than 17 years and 8 months of age
2. A documented focus of infection or a strong suspicion of infection at PICU admission, or for patients who develop septic shock during PICU stay, at the onset of the septic shock event
3. Surveillance cultures (e.g. blood, urine, cerebral spinal fluid, wound) and/or other microbial diagnostic tests have been obtained
4. One or more antimicrobials have been prescribed
5. Core temperature >38.5 C or <36.0 C or leukocytosis or leukopenia (as defined by the local laboratory) or a left-shifted leukocyte differential (>10% immature granulocyte forms) or a neutrophil count of <0.5 x 109 cells per litre documented at least once within the 24 hours preceding screening
6. Treatment with a continuous infusion of vasoactive-inotropic agent(s) to maintain mean or systolic arterial blood pressure above the age-appropriate target set by the treating clinician
7. Administration of two or more vasoactive-inotropic agents at any dose or epinephrine or norepinephrine infusion(s) alone at greater than or equal to 0.10 mcg/kg/min for >1 hour.

Exclusion Criteria:

A child receiving treatment in a pediatric intensive care unit for sepsis is ineligible for enrollment into SHIPSS if she/he meets any of the following exclusion criteria:

1. All inclusion criteria have been present for > 12 hours
2. Attending physician expects to prescribe systemic corticosteroids for an indication other than septic shock
3. Patient has received any doses of systemic corticosteroids during treatment for sepsis
4. Enrolled concurrently in a competing interventional clinical trial (formal assessment to be conducted by SHIPSS Core Committee for each potential competing trial)
5. Etomidate or ketoconazole treatment within past 48 hours
6. Patient in whom steroids are contraindicated at time of screening (e.g. treatment for systemic fungal infection, cerebral malaria, strongyloides)
7. Known or suspected hypothalamic, pituitary or adrenal disease (including patient has received acute or chronic corticosteroid administration and the physician intends to provide corticosteroid for suspected adrenal suppression)
8. Attending physician, PICU care team, or legally recognized guardians not committed to full treatment and resuscitation at the time of screening
9. Patient documented to be pregnant
10. Previous enrollment in the SHIPSS study
11. Patient admitted directly to the PICU with a thermal burn who has been in the PICU for <72 hours prior to meeting SHIPSS inclusion criteria.
12. (U.S. sites only) Patient in the custody of US protective services
13. Patient being evaluated for brain death
14. Vasoactive-inotropic agents prescribed solely for an indication other than septic shock
15. Confirmed dengue fever

Conditions & Interventions

Interventions:
DRUG: Hydrocortisone, sodium succinate, DRUG: Normal saline
Conditions:
Septic Shock
Keywords:
hydrocortisone, refractory septic shock, sepsis, new/progressive MODS, mortality, health-related quality of life, corticosteroid adverse events, sepsis biomarkers

More Information

Description:
SHIPSS is a multi-institutional, prospective, controlled, randomized, double-blinded interventional trial that will examine the potential benefits and risks of adjunctive hydrocortisone prescribed for children with fluid and vasoactive-inotropic refractory septic shock. It is hypothesized that adjunctive hydrocortisone will significantly reduce the incidence of new and progressive organ dysfunction (primary outcome) and proportion of children with poor outcomes, defined as death or severely impaired health-related quality of life (HRQL) (secondary outcome), as assessed at 28

days following study enrollment (randomization).

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