Acetaminophen and Ascorbate in Sepsis: Targeted Therapy to Enhance Recovery

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Age ≥ 18 years 2. Sepsis defined as: 1. Clinical evidence of a known or suspected infection and orders written to administer antibiotics AND 2. Hypotension as defined by the need for any vasopressor (and 1 liter of fluid already administered intravenously for resuscitation) OR respiratory failure defined by mechanical ventilation, BIPAP or CPAP at any level, or greater than or equal to 6 liters/minute of supplemental oxygen (criterion b must be met at time of enrollment) 3. Admitted to a study site ICU (or intent for the patient to be admitted to a study site ICU) within 36 hours of presentation to the ED or admitted to the study site ICU within 36 hours of presentation to any acute care hospital

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Exclusion Criteria:

1. No consent/inability to obtain consent from the participant or a legally authorized representative 2. Patient unable to be randomized within 36 hours of presentation to the ED or within 36 hours of presentation to any acute care hospital 3. Diagnosis of cirrhosis by medical chart review 4. Liver transplant recipient 5. AST or ALT greater than five times upper limit of normal 6. Diagnosis of ongoing chronic alcohol use disorder/abuse by chart review; if medical record unclear, use Appendix F 7. Clinical diagnosis of diabetic ketoacidosis or other condition such as profound hypoglycemia that requires hourly blood glucose monitoring (applicable to the 4 arm (Vitamin C/placebo vs. Acetaminophen/placebo) phase of the trial) 8. Hypersensitivity to Acetaminophen or Vitamin C 9. Patient, surrogate or physician not committed to full support (Exception: a patient will not be excluded if he/she would receive all supportive care except for attempts at resuscitation from cardiac arrest) 10. Home assisted ventilation (via tracheotomy or noninvasive) except for CPAP/BIPAP used only for sleep-disordered breathing 11. Chronic dialysis 12. Current active kidney stone (applicable to the 4 arm (Vitamin C/placebo vs. Acetaminophen/placebo) phase of the trial) 13. Multiple (>1) episodes of prior kidney stones, known history of oxalate kidney stones, or history of oxalate nephropathy. (applicable to the 4 arm (Vitamin C/placebo vs. Acetaminophen/placebo) phase of the trial) 14. Kidney transplant recipient (applicable to the 4 arm (Vitamin C/placebo vs. Acetaminophen/placebo) phase of the trial) 15. Use of home oxygen >3L/minute via nasal cannula for chronic cardiopulmonary disease 16. Moribund patient not expected to survive 24 hours 17. Underlying malignancy or other condition with estimated life expectancy of less than 1 month 18. Pregnant woman, woman of childbearing potential without a documented negative urine or serum pregnancy test during the current hospitalization, or woman who is breast feeding 19. Prisoner 20. Treating team unwilling to enroll because of intended use of Acetaminophen or Vitamin C 21. Treating team unwilling to use plasma (as opposed to point of care testing) for glucose monitoring (applicable to the 4 arm (Vitamin C/placebo vs. Acetaminophen/placebo) phase of the trial).

Conditions & Interventions

Interventions:
Drug: Intravenous Acetaminophen (room temperature), Drug: Intravenous Vitamin C (refrigerated), Drug: 5% Dextrose (room temperature), Drug: 5% Dextrose refrigerated
Conditions:
Acute Respiratory Distress Syndrome, Critical Illness, Respiratory Failure, Sepsis
Keywords:
ARDS, Acetaminophen, Vitamin C, Sepsis

More Information

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