

Targeted Reversal of Inflammation in Pediatric Sepsis-induced MODS

Status: RECRUITING

Eligibility Criteria

Age: 1 day to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* ≥ 40 weeks corrected gestational age to < 18 years; AND * Admission to the PICU or CICU; AND * Onset of ≥ 2 new organ dysfunctions within the last 3 calendar days (compared to pre-sepsis baseline) as measured by the modified Proulx criteria; AND * Documented or suspected infection as the MODS inciting event.

Exclusion Criteria:

* Weight < 3 kg; OR * Limitation of care order at the time of screening; OR * Patients at high likelihood of progression to brain death in opinion of the clinical team; OR * Moribund condition in which the patient is unlikely to survive the next 48 hours in opinion of the clinical team; OR * Current or prior diagnosis of hemophagocytic lymphohistiocytosis or macrophage activation syndrome; OR * Peripheral white blood cell count $< 1,000$ cells/mm³ as the result of myeloablative therapy OR receipt of myeloablative therapy within the previous 14 days; OR * Known allergy to anakinra, or E. coli-derived products; OR * Known pregnancy; OR * Lactating females; OR * Receipt of anakinra within the previous 28 days; OR * Resolution of MODS by MODS Day 2; OR * Previous enrollment in the TRIPS study.

Conditions & Interventions

Interventions:

DRUG: Anakinra, DRUG: Placebo

Conditions:

Pediatric Sepsis-induced Multiple Organ Dysfunction Syndrome (MODS)

More Information

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Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT05267821

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