

Targeted Reversal of Inflammation in Pediatric Sepsis-induced MODS

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 1 day to 17 years old

Healthy Volunteers: This study is NOT accepting healthy 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

Description:

The TRIPS study is a prospective, multi-center, double-blind, adaptively randomized, placebo-controlled clinical trial of the drug anakinra for reversal of moderate to severe hyperinflammation in children with sepsis-induced multiple organ dysfunction syndrome (MODS).

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Principal Investigator:

Principal Investigator ID:

Phase: PHASE2

IRB Number:

System ID: NCT05267821

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