

Open-Label Study to Assess Safety and Time to Catheter-related Bloodstream Infections (CRBSI) in Subjects From Birth to < 18 Years of Age

NCT06714864

Status	RECRUITING
Phase	Phase 4
Sponsor	CorMedix
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (21)

- The investigator, or a person designated by the investigator, will obtain written informed consent from each study participant's legal guardian and the participant's assent, when applicable, before any study-specific activity is performed. All legal guardians should be fully informed, and participants should be informed to the fullest extent possible, about the study in language and terms they are able to understand.
- A legal guardian or primary caregiver must be available to help the study-site personnel ensure follow up; accompany the participant to the study site on each assessment day according to the schedule of activities (SoA) (e.g., able to comply with scheduled visits, treatment plan, laboratory tests and other study procedures); consistently and consecutively be available to provide information on the participant during the scheduled study visits; accurately and reliably dispense study intervention as directed.
- The participant has kidney failure and undergoes chronic hemodialysis (HD) at least 2 times per week.
- The participant has an HD central venous catheter (CVC) and is placed in a jugular or subclavian vein.
- The participant has demonstrated the ability to achieve an appropriate minimum blood flow (Qb) for the participant's relative age and weight for at least 2 consecutive dialysis sessions to enable successful HD.

... and 16 more (see full listing online)

Exclusion (24)

- The participant has received systemic antibiotics within the last 14 days. Topical antibiotic use is permitted.
- Visible evidence of compromised skin integrity is present at the catheter exit site or evidence of a catheter exit site infection.
- The participant has received any thrombolytic treatment (i.e., tissue plasminogen activator [tPA] - Cathflo®), not as part of the institution's standard of care for patency management, in their current catheter within 30 days of randomization.
- The fill volume of catheter lumen(s) is unknown or cannot be determined.
- The participant uses any type of antimicrobial-coated or heparin-coated catheter.

... and 19 more (see full listing online)

Locations (4 total)

Children's of Alabama/University of Alabama, Birmingham, Alabama, United States
Stanford, Palo Alto, California, United States
Nemours Children's Hospital - DE, Wilmington, Delaware, United States

... and 1 more locations