

A Phase III, Open Label, Randomized, Controlled Study of VBI-S in the Treatment of Hypovolemia in Patients With Septic Shock (VBI-S-02)

NCT06072430

Status	RECRUITING
Phase	Phase 3
Sponsor	Vivacelle Bio
Enrollment	46 participants

Key Eligibility Criteria

Inclusion (17)

- Male or female at least 18 years of age.
- Evidence of bacterial infection demonstrated by positive blood culture and/or a known source of infection and/or an elevated procalcitonin of ≥ 2 ng/ml.
- Patient has a mean blood pressure < 65 mmHg that is unresponsive to fluids currently available on the market.
- Sequential Organ Failure Assessment (SOFA) score ≥ 5
- Sepsis diagnosis: The presence of infection which can be proven or suspected by 2 or more of the following criteria:
... and 12 more (see full listing online)

Exclusion (14)

- Patients with a ventricular assist device
- Acute coronary syndrome
- Pregnant
- Acute bronchospasm
- Acute Mesenteric ischemia
... and 9 more (see full listing online)

Locations (6 total)

Dignity Health Chandler Regional Medical Center, Chandler, Arizona, United States
Memorial Health University Medical Center, Savannah, Georgia, United States
University Health, Kansas City, Missouri, United States
... and 3 more locations