

Compassionate Use of Berlin Heart EXCOR Pediatric Ventricular Assist Device

Berlin Heart Inc. is sponsoring a prospective, multi-center, single arm study to assess the safety and probable benefit of the Berlin Heart EXCOR® Pediatric Ventricular Assist Device (EXCOR® Pediatric). The study will compare the EXCOR® Pediatric with a historical control population supported with ECMO as bridge to cardiac transplantation in children. The expected duration of the study is up to five years with subjects consented for participation for that long. Vanderbilt will not be a study site for Berlin Heart Inc. We are applying for use of this device for compassionate use for patients with severe heart failure who are listed for orthotopic heart transplant and who are in need of mechanical support as a bridge to transplant.

The purpose of the study is to

- Specific Aim 1:** Determine whether use of the Berlin Heart EXCOR® Pediatric VAD for bridge-to transplantation is associated with reasonable assurance of safety and probable benefit such that the EXCOR® Pediatric merits approval by the Food and Drug Administration (FDA) under a Humanitarian Device Exemption (HDE).
- Specific Aim 2:** In addition, the study will determine whether the EXCOR® Pediatric merits continuation with the current trial design and subject population to prove safety and efficacy for Pre-Market Approval (PMA).