What is the purpose of the study?
New devices are being developed that can possibly help support the child/person whose heart function is not providing enough blood flow to their body. One device is the Berlin Heart EXCOR® Pediatric Ventricular Assist Device (or simply “EXCOR® device”). This device has small pumps that can be used to support the left or right or both sides of a patient’s heart. The pump or pumps is/are connected to cannulae (tubes) that are sewn onto the child’s heart. The pump is driven by a machine outside of the child’s body, to pump the blood through the child’s heart. This may help improve the blood flow to the child’s body.

Who is eligible to participate in the study?
Subjects who are candidates for heart transplants with no available organ may be eligible to participate. Patient should be recommend by their physician for mechanical support of his/her own heart as best prospect for surviving until a heart becomes available.

What does the study involve?
Subjects will have tests performed before and after the EXCOR® device is inserted. These tests are similar to the tests done prior to implant and include: a medical history, physical exam, heart rate and blood pressure measurement, urine output, a record of medications, and blood tests. The device will be implanted in the operating room using surgery with the subject’s chest open, similar to traditional heart surgery. The subject will be placed on a ventilator and will remain on the machine until the physician feels he/she is able to breathe on his/her own. The chest will be opened to insert the cannulas (tubes) that will be connected to the EXCOR® blood pump(s) and the physician will start the pump(s). The pumps are located outside the child’s body.

After the surgery subjects will be transferred to the Intensive Care Unit until he/she wakes up from the surgery and is stable enough to be move to a step down unit.

What are the benefits?
There is no guarantee of direct benefit from participating in the implantation of this device. Subjects may receive no benefit from implantation of the EXCOR® Pediatric. Possible benefits may include enough mechanical support for the patient to undergo a heart transplant operation, protection from further heart and organ damage; reduced work load on the heart, and increased blood flow and oxygen delivery and supply to other parts of the body.

What are the risks?
There are risks associated with this type of device that are similar to those risks identified with other heart assist devices and with heart (cardiac) surgery. It is possible that these risks could result in serious or permanent injury or disability.

Is there any compensation for participating?
There is no compensation for participation in this study.
How will I get more information about the study?
Interested parents will discuss the study with a member of the research team and will be given a parent permission/consent form that further explains all of the details of the study. Study procedures will not be started until the parent(s) fully understands what is involved in the study and has signed a parent permission/consent form.

**Status:** Recruiting  
**Site(s):** Advocate Children’s Hospital, Oak Lawn Campus, Advocate Children’s Heart Institute

**Who should I contact for more information?**  
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