What is the purpose of the study?
The purpose of this study is to gather more information about how effective the AMPLATZER® Muscular VSD Occluder is at closing holes in the heart, as well as collect information about the safety of the device.

Who is eligible to participate in the study?
Children with a ventricular septal defect may be eligible to participate.

What does the study involve?
Each eligible child will have baseline testing to determine if (s)he qualifies for the study. Those who do qualify will have an implant procedure in the cardiac catheterization lab, or “cath lab”. Blood samples and pressures from the child’s heart may be measured during this procedure. This is a non-surgical procedure done using x-ray guidance in which a catheter is inserted through a blood vessel in the thigh or neck into the heart. To help the physician evaluate the VSD during the procedure, participants will have Transesophageal Echocardiography (TEE), angiography and maybe intracardiac echocardiography (ICE) done. TEE is a type of echocardiogram (also called an echo), which is an ultrasound test that allows the doctor to look at the chambers of the heart using sound waves. Angiography is an x-ray of blood vessels or heart chambers filled with a contrast dye that allows the doctor to see moving pictures of the heart. ICE is an invasive diagnostic test using a catheter with a sound transducer (or sound probe) on the end. The catheter is advanced through a vein in the groin and positioned in the heart. High-frequency sound waves are used to create precise images of the interior heart chambers and valves. After evaluating the VSD, the doctor may decide it is best not to attempt to close it with an AMPLATZER® Muscular VSD Occluder. Otherwise, the doctor will attempt to close the hole in the heart using the AMPLATZER® Muscular VSD Occluder. The procedure is expected to last for approximately 2-4 hours. Depending on the number of VSDs and/or the size of the VSD(s), more than one VSD occluder may be placed in participant’s heart. Participants should avoid strenuous activity for one month after the implant procedure. Participants may be prescribed aspirin (or other antiplatelet/anticoagulation medication) and/or an antibiotic (infection-fighting) medicine for 6 months following device implantation. Participants will have follow-up visits with their doctor approximately one day, 30 days, 6 months, and one year after the procedure; then yearly visits for approximately five years.

What are the benefits?
There is no guarantee of direct benefit by participating in this study. The results of this study may provide information that could help other children with VSDs in the future.

What are the risks?
As with any invasive procedure, there are certain risks involved with both surgery and the use of the Amplatzer Septal Occluder device. These will be discussed in detail by the research team prior to enrolling in this study.

Is there any compensation for participating?
Participants may receive up to $400 total ($50 per visit) for completing all visits.

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 Hope Children’s Hospital, The Heart Institute for Children (THIC)

**Who should I contact for more information?**
Julie Connolly, RN
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