

PEDIATRIC HEART DISEASE CLINICAL RESEARCH NETWORK



*Information for Hypoplastic Left Heart
and other Single Right Ventricle
Patients and Their Families*

The purpose of this brochure is to provide you with information regarding an important research study funded by the National Heart, Lung, and Blood Institute. This study is being conducted at up to 15 other medical centers in the U.S., Canada, and Europe. Your child is being asked to be in this study because he or she needs a Norwood operation. The purpose of this research is to find out which of two different shunts is best for patients who undergo the Norwood operation.

What is a Shunt?

This research study involves the positioning of the shunt (a small tube) that is placed to deliver blood from the heart to the blood vessels in the lungs (pulmonary arteries). There are two possible positions for this shunt. Traditionally, the position for the shunt is from a branch off of the aorta, (the major blood vessel that takes blood from the heart to the rest of the body) to the pulmonary artery. This standard shunt is called a modified Blalock-Taussig shunt (MBTS). The other type of shunt is placed between the right ventricle (pumping chamber of the heart) and the pulmonary arteries and is called an RV-to-PA shunt.

How do I join?

In order for your child to participate in this study, he/she must meet certain specific criteria, and you must sign an Informed Consent Form. If you agree to allow your child to participate in this study, we will review and record information from your child's medical chart about your child's heart problem and any other medical problems and how the heart condition has been treated.

What tests are required during the study?

During the 14 months of the study, your child will undergo tests to evaluate your child's development and how your child's heart is functioning. Information about how your child is doing will be collected from your child's medical records. There is one required study visit when your child is 14 months old. This visit may be part of a regularly scheduled visit to your child's doctor.

As part of this study, you and your child will participate in the following:

Questionnaires: When your child is 14 months old, you will be asked to fill out three questionnaires. The first questionnaire describes your child's general health and level of physical function. The second questionnaire measures your child's ways of communicating (talking and

gestures). The third questionnaire asks questions about your family setting and your current occupation.

In addition, a specially trained person will evaluate your child's level of development - for example, whether your child can walk and talk, and how he/she plays with toys. Your child's doctor will be given the results of this evaluation to share with you.

Echocardiograms: An echocardiogram is a painless test using sound waves that takes a picture of your child's heart and is performed routinely in all children with heart disease. We will record information from the echocardiograms your child's cardiologist orders as part of your child's routine care. Your child may have one extra echocardiogram for study purposes at age 14 months. Your child will need to lie quietly on a table for about 30 minutes while the echocardiogram is being done. The echocardiogram may require sedation (a medicine to allow your child to lie still) since children this age are often active.

Cardiac Catheterization: If your child has a routine cardiac catheterization ordered by your child's cardiologist before the stage II surgery, the information from the test will be recorded for the study. Your child does not need to have a cardiac catheterization done to participate in this study.

Is there any cost?

Tests required by the study that are not part of your child's regular care will be provided to you free of charge. The study will also pay for travel expenses and a meal on the day(s) your child is scheduled for tests related to the study that are not part of the routine care. If you live far away from the study center and an overnight stay is required to complete study testing, you will be reimbursed for one night's lodging and meals.

Can I withdraw?

Your decision to have your child participate in this study is completely voluntary. You may refuse to give permission to participate or you may withdraw your child from the study at any time. Refusal to participate or withdrawal from the study will not affect your or your child's medical care now or in the future.

Confidentiality

You have a right to privacy and your child's participation in this research study will remain confidential. Your child's name will not be used in any published report of information from this study.

Your and your child's participation in this research study will help to contribute to a better understanding of the best way to treat children with a single ventricle. Please consider taking part in this important research endeavor.