

PEDIATRIC HEART DISEASE CLINICAL RESEARCH NETWORK



Information for Infant Single 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 done at seven medical centers in the U.S. and Canada to find out whether an ACE Inhibitor drug called enalapril will improve growth and heart function during the first 14 months of life.

What is Enalapril?

Enalapril is a drug that has been shown to improve heart function in adult patients with heart failure. It is part of a class of drugs called angiotensin converting enzyme (ACE) inhibitors. The beneficial effects of enalapril may also be seen in infants with single ventricle but it has not been studied in these patients.

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 to get background information about your child's heart problem and any other medical problems your child has had 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. There are six required study visits during the 14 months. Some of the visits and/or tests that are planned 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:

Measurement of growth: Your child will have his/her weight, height and head circumference measured at each visit.

Questionnaires: When your child is 14 months old, you will be asked to fill out two 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).

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. Your child may have up to two echocardiograms for study purposes. Your child will need to lie quietly on a table for about 30 minutes while the echocardiogram is being done. The echocardiogram at age 14 months may require sedation (a medicine to allow your child to lie still) since older infants are more active.

Blood Tests: Your child will have three blood tests done during the 14 months to make sure that it is safe for him/her to continue taking the study medication. In addition, the level of B-Type Natriuretic Peptide (a protein made by the heart) in your child's blood will be measured twice: once during his or her regularly scheduled catheterization or surgery (the bi-directional Glenn shunt or Hemi-Fontan surgery) and another time at 14 months of age. Prior to drawing the blood sample at the 14 month visit, a cream that numbs the skin will be placed on the area where the blood will be drawn and your child will lie quietly for 15 minutes. The total amount of extra blood drawn for this study, will be less than one teaspoon (less than 5 ml).

Cardiac Catheterization: If your child has a routine cardiac catheterization ordered by your child's cardiologist before the bi-directional Glenn shunt or hemi-Fontan 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 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. 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. If you choose to allow your child to participate in this study, you will obtain information regarding your child's heart condition, as well as his or her mental and physical development. Please consider taking part in this important research endeavor.