



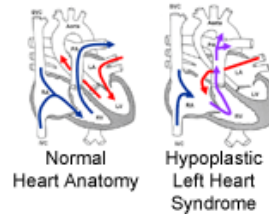
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### ISV Study Basics

ISV is a Trial of *ACE Inhibition* in Infants with Single Ventricle. The short title for the study is ISV. This study is being done to see if giving a medication called Enalapril (an ACE inhibitor) will improve your child's growth and heart function in the first year of life. ISV will enroll 230 babies. The study began on August 25, 2003 and will last for 43 months.

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### Who can be in the study?

Your child can be in the study if they:

- Are currently less than 45 days of age and stable
- Have a single *ventricle* (lower pumping chamber) heart instead of 2 ventricles
- Were born no earlier than 35 weeks and weigh at least 2.5 Kg at birth (about 5½ pounds)
- Plan to have a Glenn shunt surgery
- Have not been on an ACE inhibitor for more than 7 days

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### What do we have to do to be in the study?

If your child meets the requirements, the study will be explained to you in detail by one of the *study investigators*. Once your questions have been answered, you will be asked to sign an *informed consent* form to allow your child to enter the study. Some of the things that will happen during the study may be done only for study purposes. We will make every attempt to time the tests required for the study with your child's routine visits. We will also collect information on blood work and procedures that your baby gets as part of routine clinical care. The process begins when your child is *randomly assigned* to a group to receive either Enalapril or a *placebo* (a sugar solution).

During the 14 month study period, the following data will be collected:

- When the study drug is first started, your child's blood pressure and oxygen level will be monitored every 30 minutes for 2 hours.
- A blood test will be done 4 and 14 days after starting the drug to make sure that the medicine is being well tolerated. This blood test will be repeated prior to the Glenn surgery and again at 14 months.
- An *echocardiogram* will be done prior to starting the study, prior to the Glenn surgery and again at 14 months.
- Your child's height and weight will be checked prior to starting the drug, at 14 days, prior to the Glenn surgery and again at 14 months.
- A full *neurodevelopmental examination* will be done at 14 months of age.

Study personnel will be in contact with you frequently during the time your child is in the study. You are free to call the nurse or study coordinator with any questions or concerns that you may have. Some study visits may be able to be done at your local cardiologist's office. Please discuss this with your study team.

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### How long will we be in the study?

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Your child will be followed for 14 months.

#### **What are the possible benefits to being in this study?**

Although your child may not directly benefit from being in this study, your participation will enable your doctors to better understand whether Enalapril therapy helps infants with single ventricle heart disease to grow better and to have improved heart function. Your child will receive a neurodevelopmental evaluation as part of this study. The results of this evaluation will let you know if there are developmental concerns and if early intervention should be considered.

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#### **What are the possible risks to being in this study?**

Rarely, infants experience undesirable side effects from ACE-I therapy. The most common *side effect*  is lowered blood pressure. All of the possible risks and what will be done to help prevent them will be discussed in detail by the study doctor or nurse before asking for your consent to participate.

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#### **What are the costs to me to be in the study?**

There will be no additional costs to you if your child participates in this study. Tests required by the study and that are not a part of your child's regular care will be provided free of charge. You are responsible for all other costs related to your child's medical care such as hospitalization, surgery, drugs, lab tests and physicians fees which are considered standard medical care.

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ISV For Healthcare Providers 