



Pediatric Heart Network
Funded by the NHLBI

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SVR Study Basics

SVR is a Trial of Right Ventricular vs. Modified Blalock-Taussig Shunt (MBTS) in Infants with Single Ventricle Defect Undergoing Staged Reconstruction. The short title for the study is Single Ventricle Reconstruction (SVR). Your baby was born with a single ventricle heart instead of the standard two ventricles which requires a series of operations. The first one is called the *Norwood procedure*. This operation involves placing a *shunt* to carry blood from the heart to the lungs. This study will evaluate two commonly placed shunts to see if one will improve how patients do following the Norwood operation. The study will enroll 466 babies. SVR began on May 1st, 2005 and will last for 33 months.

Who can be in the study?

Your child can be in the study if they:

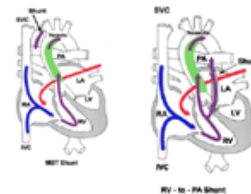
- Have a single ventricle (lower chamber) heart instead of the normal 2
- Will have the Norwood surgery

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. Your child will:

- Be *randomly assigned* to a group to receive either the *MBT shunt* or the *RV-to-PA shunt*.

Click for larger image:



- Be seen before and during the hospitalization for the Glenn surgery.
- Be seen 14 months after the surgery, have an *echocardiogram*, a *neurodevelopmental examination*, and perhaps a *genetic evaluation*.

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.

How long will we be in the study?

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 allow your doctors to better understand which type of shunt may be better for children who undergo a Norwood procedure. 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

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concerns and if early intervention should be considered.

What are the possible risks to being in this study?

Your child has a serious heart defect that includes serious risks that are not associated with this study. Risks related to this study are associated with the type of shunt that is placed, not as a direct result of being in the study. It is important to talk with your healthcare providers about these risks. Other possible risks and what will be done to help prevent them will be discussed in detail by the study doctor or nurse.

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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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SVR for Healthcare Providers 