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SVR Extension Study Basics

Infants with *single ventricle heart defects*  were enrolled in the Single Ventricle Reconstruction (SVR) study to look at how they did after the first stage of surgery (*Norwood operation*)  where babies got one of two kinds of shunts: a modified Blalock-Taussig shunt (*MBTS*)  or right ventricle to pulmonary artery shunt (*RV-to-PA shunt*) .

Now we would like to learn if these same children (2-6 years of age) do better with one of the two shunts (RV-to-PA or MBTS) in the years after surgery. Also we want to see how other medical and surgical factors affect children's health and how they develop.

 = glossary definition

How many people will be in the study?

All children who were enrolled in the original SVR study will be invited to participate.

When will the study start?

May 2008

How long will the study last?



This study will continue until 2015.


Who can be in the study?

Your child can be in the study if he or she was enrolled in the first SVR study.

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

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 enter the study. This is what needs to be done in the study:

- **Medical Record Review:** We will look at your child's medical chart and contact you every year starting when your child reaches 2 years of age until your child is 6 years old. You may be asked to sign a form allowing us to get data from other places where your child gets care.
- **Echocardiogram (Echo)** : We will collect data about your child's heart function from echos that your cardiologist ordered as part of regular clinical care at two time points.
- **Electrocardiogram (ECG)** : We will obtain a copy of your child's ECG that is usually done before the Fontan procedure and again at around 6 years of age. The ECG is done as part of regular clinical care and not for research purposes.

- **Holter Monitor** : At 6 years of age we will want to measure your child's heart rate and rhythm with a Holter monitor. If your child's cardiologist orders this test at about 6 years of age for routine clinical reasons, we will ask for the results. Otherwise, the Holter monitor will be done as part of the study.
- **Neurodevelopmental Questionnaires**: We will mail surveys to your home and ask you to fill them out when your child is 3, 4, 5 and 6 years of age. They will ask about your child's physical abilities, behavior, health, and quality of life.

Study personnel will be in contact with you during the time your child is in the study. You are free to call the nurse or study coordinator at any time with any questions or concerns that you may have.

How long will we be in the study?

We will follow your child through 6 years of age. When you agree to join this study the nurse or doctor will also contact you once each year by a brief telephone call or letter, until your child is 11 years of age. We will ask about how your child is doing and describe any further follow-up studies that may be planned in the future. You are not committed to entering any other studies.

What are the possible benefits to being in this study?

Although you or your child may not directly benefit from being in this study, your participation will allow your doctors to better understand how babies with Single Ventricle repair do after surgery and as they grow up. Past studies on children with other types of heart defects have learned a great deal of information with a similar approach.

What are the possible risks to being in this study?

Possible risks may be inconvenience and minor skin irritation from the patches placed on the skin during the Holter monitor. You may find it inconvenient to complete the surveys or to talk with the study nurses by phone. We will give you plenty of time to fill out the forms. You do not have to answer any questions that make you feel uneasy.

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

There will be no extra costs for being in this study. Tests needed by the study and that are not a part of regular care will be provided free of charge. You must pay 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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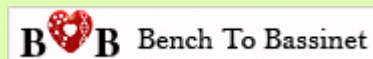
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