The purpose of this study is to evaluate newly developed treatments available for babies with small left heart structures, including the main pumping chamber of the heart and the vessel that distributes blood from the heart to the rest of the body. This heart defect is known as critical left ventricular outflow tract obstruction (LVOTO) and is present in 8% of babies born with heart defects. New treatment options include changes in the way corrective surgery is performed and other interventions that may decrease the number of operations that your child may need in order to repair their heart. This study will help your child’s physician decide which treatment is the best one for your child.

Description of the Research:

This study is being done at Sick Kids’ Pediatric Cardiovascular Surgery Department. Dr. Christopher Caldarone, the Principal Investigator, is in charge of this study along with the Congenital Heart Surgeons’ Society (CHSS).

The CHSS is a group of 75 pediatric heart surgeons that is devoted to the study of infants with heart defects. This group collects information on children with congenital heart disease from many different centers in Canada and the United States. This information is kept in a secure and confidential registry at the CHSS Data Center, at Sick Kids in Toronto. Since children with congenital heart disease have many different and sometimes rare conditions, gathering information from many centers gives us better information on how children with congenital heart disease are doing. We also learn what factors and treatments have a better or worse result. This is especially important in babies with LVOTO because of the new treatment options that are now available. The CHSS Data Center helps surgeons and cardiologists decide what the best treatment is for your child and helps your child’s doctor give you and your child accurate and up-to-date information about their prognosis.
We are asking you to let your child participate in this study because he/she was born with critical LVOTO. About 75 surgeons will be enrolling children in this study at 45 different hospitals throughout North America. Sick Kids will enroll approximately 2 patients per month in this study.

This is an observational study, and does not involve medicines or other than those that your child would normally need. Information about your child’s hospitalization will be sent to the CHSS Data Center. Information such as your name and address, and your child’s name and address, your child’s diagnosis, pediatrician’s name and address, medical and surgical reports, copies of echocardiograms, chest x-rays, and cardiac catheterizations will be entered into a password protected computer database. Once this information is collected, a unique study identification number will be created for your child so that personal health information is not used directly in any further analysis or correspondence. De-identified videotapes or compact discs of your child’s echocardiograms, linked only to your child by a unique study identification number, will also be securely forwarded to the Data Center.

At yearly intervals, healthcare professionals from Sick Kids or the CHSS Data Center will call and/or mail a letter to you to find out how your child is doing. The letter is a survey that you will be asked to complete and return regarding your child’s health. These healthcare professionals may also ask questions about the medication your child is receiving, and surgery or procedures done during the year. At five year intervals, you/your child will be contacted by phone and/or mail, and asked to complete an additional questionnaire regarding your child’s quality of life. This information will be analyzed together with that from other children with the same heart defect from the other centers to determine the impact of patient factors and different treatments on results and to examine the overall health status and quality of life of children with critical LVOTO. We would like to continue to follow the patients who participate in this study for up to 15 years. By agreeing to participate in this study you are giving permission for the investigators to contact you annually as mentioned above.

If changes are made to the study or new information that might affect your willingness to continue to participate in the research becomes available, you will be informed.

Potential Harms:

There are no known harms associated with participation in this study. If you agree for your child to participate in the study, your child’s diagnostic testing, surgery, or other interventions will not be altered in any way. All records associated with your child’s participation will be kept strictly confidential within the CHSS Data Center registry. His or her personal health information will not be released to any outside individuals or used in any publication. There are no consequences if you do not agree on behalf of your child to participate in the study.

Participation in this study will not prevent your child from participating in any other research study, including the National Institute of Health Single Ventricle Reconstruction Trial.

Potential Discomforts or Inconvenience:
There are no potential discomforts or inconveniences associated with participation in the study.

Potential Benefits:

To individual subjects:

Consent/Assent Form Version Date January 18th, 2007
The information collected by this study may contribute to the care of children in the future who have the same heart condition as your child. The information may also improve the future management of your child. However, your child will not benefit directly from participating in this study. Results of the study will not be shared directly with you or your child; however, it will be available in the scientific publications resulting from this work.

To society:
Society in general or patients with a similar heart condition may benefit from the results of this study, as explained above.

Confidentiality:
You and your child have rights regarding the privacy and confidentiality of your child’s health information. When health information includes identifiers (like names, addresses, phone numbers and) that link it directly to an individual, it is called protected health information (PHI). Provincial and federal laws both require that PHI be kept secure and private. In certain situations, federal law also requires that you approve how your child’s PHI is used or disclosed. A research study is one of those situations.

By signing this consent form, you are allowing the following people access to your child’s medical record and use of your child’s PHI for the research purposes described in this form:

- The research team, which includes the study personnel listed on this form and other persons involved in this study at Sick Kids
- The Congenital Heart Surgeons’ Society and the Data Center Staff
- The Ethics Review Board at Sick Kids
- Federal and provincial regulatory agencies such as the Office of Information and Privacy Commissioner/Ontario and the Office of Human Research Protection

Information about your child that is obtained during this study will be recorded in a research record. Information in the research record will be sent to the CHSS Data Center (the sponsor). These records will include you and your child’s name, address and telephone number, your child’s medical record number, hospital account number, and date of birth.

The research record is separate from your child’s medical record. Information from your child’s medical record may also be recorded in the research record. By signing this consent form, you are allowing your child’s information to be recorded in the research record. You are also permitting your child’s research record to be shared with the Congenital Heart Surgeons’ Society and the Data Center Staff.

Confidentiality will be respected and no information that discloses the identity of the subject will be released or published without consent unless required by law. This legal obligation includes a number of circumstances, such as suspected child abuse and infectious disease, expression of suicidal ideas where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities. For your information, the research consent form will be inserted in the patient health record. Health records identifying the patient may be given to and inspected by the Sick Kids Clinical Research Office Monitor.

Reimbursement:
You nor your child will be reimbursed for participation in this study.

**Participation:**

Participation in research is voluntary. If you choose on behalf of your child to participate in this study you can withdraw your child from the study at any time and no new information about your child will be collected for study purposes. You and your family will continue to have access to quality care at HSC.

New findings developed during the course of the research which may impact on your willingness to continue will be provided to you and your consent will be requested again, if necessary. You will be given a copy of this consent form for your records.

If your child becomes ill or are injured as a result of participation in this study, medical treatment will be available at no additional cost to you. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.

**Sponsorship:**

The sponsor of this research is the Congenital Heart Surgeons’ Society (CHSS). In certain situations, this study may be cancelled at the discretion of the investigator or the study sponsor even if you are benefiting personally. If this occurs, the investigator will discuss next steps with you.

**Conflict of Interest:**

The investigator for this study, Dr. Christopher Caldarone, declares that on behalf of himself and the research team, there are no conflicts of interest regarding the study.
**Consent:**
By signing this form, I agree that:

1) The study has been explained to me. All my questions were answered.
2) The possible harms and discomforts and the possible benefits (if any) of this study have been explained to me.
3) I know about the alternatives to having my child take part in this study. I understand that I have the right to refuse their participation and the right to stop at any time. My decision about whether or not to participate will not affect my child’s health care at The Hospital for Sick Children.
4) I am free now, and in the future, to ask any questions about the study.
5) I have been told that my child’s medical records will be kept confidential, except where release of information is required by law, e.g., suspected child abuse, public health.
6) I understand that no information that would identify my child will be released or printed without asking me first.

I hereby consent for my child ____________________________ to participate.

I have read and understood this consent form.

________________________________________
Name of Parent

________________________________________
Signature & Date

The Person who may be contacted about the research is:

Geraldine Cullen-Dean, R.N., M.N.

who may be reached at telephone #:

416-813-8477

________________________________________
Name of person who obtained consent

________________________________________
Signature & Date

For answers to questions about research subjects’ rights and research-related injury, please contact the Research Ethics Board Manager at (416) 813-5718.