Consent to Participate in a Research Study
Participant Consent

Study Title: Transposition of the Great Arteries: Prenatal Anatomical and Hemodynamic Findings associated with Perinatal Outcomes

Principal Investigator (Study Doctor):

Dr. Edgar Jaeggi	Head, Fetal Cardiology	(416) 813-7466

Co-Investigator(s):

Dr. Mika Saito	Cardiology Fellow	(416) 442-6953
Dr. Mike Seed	Head, Pediatric Cardiology	(416) 370-5163
Dr. Davide Marini	Cardiology MRI Fellow	(416) 813-7500

Collaborator(s):

Dr. Fraser Golding	Staff, Cardiology	(416) 813-6140
Dr. Vitor Guerra	Staff, Cardiology	(416) 813-5922
Dr. Mark Friedberg	Staff, Cardiology	(416) 813-7239
Dr. Lynne Nield	Staff, Cardiology	(416) 813-7654 ext. 228626
Dr. Varsha Thakur	Staff, Cardiology	(416) 813-7654 ext. 202604
Dr. Luc Mertens	Staff, Cardiology	(416) 813-7418
Dr. Shi-Joon Yoo	Staff, Diagnostic Imaging	(416) 813-6037
Dr. Steven Schwartz	Head, Critical Care Medicine	(416) 813-6186

Study Coordinator(s)/Research Contact:

Diana Balmer-Minnes	Research Associate Cardiology	416-813-7654 ext. 228624

24-Hour Contact Information:

Dr. Edgar Jaeggi	Phone: (416) 813-7466	Pager: (416) 232-4531

Locating Number: 416-813-7500
Please ask for the on-call doctor and let them know that you are a study participant under Dr. Jaeggi

Study Sponsor:

- Dr. Edgar Jaeggi and the Hospital for Sick Children

Study Funders:

- Labatt Family Heart Center, The Hospital for Sick Children
- Thrasher Foundation

- CHILD-BRIGHT

Conflict of Interest:
Dr. Edgar Jaeggi and the other research team members have no conflict of interest to declare.

Introduction
We would like to invite you and your baby to take part in our research study. This consent describes the research study and what it means to participate. Before deciding to take part, please take as much time as you need to ask any questions you have. You are encouraged to discuss with family, friends, your personal physician or other health professional, or any members of your community that you trust if that is helpful to you. Participation in any research study is voluntary (you do not have to participate if you don't want to).

Why am I and my baby being asked to participate?
You and your baby are invited to participate in this research study because your baby has been diagnosed with a heart condition called transposition of the great arteries (TGA). TGA is a condition, where the two main arteries of the heart are reversed. As a result, blood circulation is affected. In normal children, oxygen-poor blood flows from the heart to the lungs to become oxygen-rich, while oxygen-rich blood flows from the heart to the rest of the body. However, in babies with TGA, the opposite occurs, where oxygen-poor blood flows from the heart back to the body, and oxygen-rich blood returns back to the lungs.

Why is this study being done?
A diagnosis of TGA during the pregnancy is helpful as it allows more rapid treatment after birth. Current treatment for TGA at birth include medications, receiving critical cardiac care and undergoing surgical interventions. Although such treatment tends to be provided in a timely manner, some babies can still become very sick almost immediately after birth. The aim of this study is to better identify which newborns with TGA will require more urgent care at birth so that the appropriate treatment and management options can be provided early, resulting in better health outcomes. We would like to do this by looking at blood and oxygen flow in the baby's brain and heart using echocardiography (ultrasound exam of the heart) and magnetic resonance imaging (MRI) before and during oxygen that is given to the mother. MRI uses a strong magnet and radio-waves to take pictures of the baby through the mother's body while lying still inside the scanner. Echocardiography and MRI are both harmless techniques that we use on a regular basis during pregnancy and after birth. In combination with MRI and echocardiography, maternal oxygen will be administered for a short amount of time to help with identifying babies who are at higher risk. We believe that the unborn baby's response to oxygen may help in predicting if the newborn will remain well or will be unwell and unstable early after delivery. If confirmed, our approach may be used to better guide the neonatal management of babies with TGA.

What other choices are there?
You may choose not to take part in this research study. This will not affect the quality of care you would otherwise receive. As part of standard of care, you will continue to undergo tests, and echocardiogram and MRI scans as needed. Your physicians will continue to determine the necessity and frequency of

pregnancy tests and scans according to the regular practices.

How many participants will be in this study?

We will study up to 50 pregnancies with TGA at SickKids.

How long will the study take?

The study visit will take about 1-2.5 hours to complete. We will try to arrange the echocardiogram and fetal MRI at the same time so that you only need to complete one visit for the study. In the case where both tests cannot be scheduled at the same time, you will need to come in for another visit to complete the remaining test. Once we have obtained your consent to participate, your child will remain in this study during the 1st year of life, where we will continue to access your child's medical records to collect relevant data. Other patient visits and exams will be decided by your cardiologist and will not be study-related. Overall, this study will take about 2 and a half years to complete and another year to publish the study results.

What will happen if you and your baby join this study?

As part of the standard of care for babies with TGA, we routinely do a fetal echocardiogram and MRI at 34 gestational weeks or later. If you decide to participate in the study, you will also be given oxygen for up to a maximum duration of 30 minutes by mask during both the echocardiogram and 45 minutes during the MRI. The echocardiogram and MRI will be done before and during the time you are being given oxygen.

What are the study procedures?

During the study, we will ask you to do the following things for this research study:

Maternal Hyperoxygenation:

An echocardiogram and fetal MRI will be performed prior to oxygen supplementation (baseline) as per standard of care. An additional echocardiogram and fetal MRI will be performed during oxygen administration for research purposes. Following the baseline echocardiogram, you will be asked to wear an oxygen mask for a maximum duration of 30 minutes during the echocardiogram and 45 minutes during the MRI. Both the echocardiogram and MRI will be arranged at the time of your last pregnancy visit with us at 34-weeks or later.

Fetal MRIs and Echocardiograms:

A fetal MRI and echocardiogram will be performed before (as part of standard of care) and during oxygen administration (for research purposes) in order to look at blood flow patterns in your baby's brain and heart. The echocardiogram will take about a total of an hour to complete, and the MRI will take a maximum of 90 minutes. Both tests can be done on the same day or separate days, depending on availability of the echocardiogram and MRI.

In addition to the data collected during study procedures, we ask you to provide us with permission to access your and your baby's patient charts for medical information about your pregnancy, delivery and

after birth to a maximum of 1 year of life for this research study. All the information will be collected from medical records available at SickKids.

Below is a table summarizing the study procedures:

Study Procedure	Screening	Visit 1 [34 or later gestation]	Visit 2 [if echocardiogram or fetal MRI not completed during Visit 1]
Length of visit	Varies – depends on clinical visit	1-2.5 hours	1 - 1.5 hours
Informed consent	X		
Maternal Hyperoxygenation (research-specific)		X	X*
Echocardiography (prior to oxygen – SoC; during oxygen research-specific)		X	X*
Fetal MRI (prior to oxygen – SoC; during oxygen research-specific)		X	X*

SoC – standard of care
*If both echocardiogram and fetal MRI cannot be completed during Visit 1, the remaining test will be completed before and during oxygen on a separate day

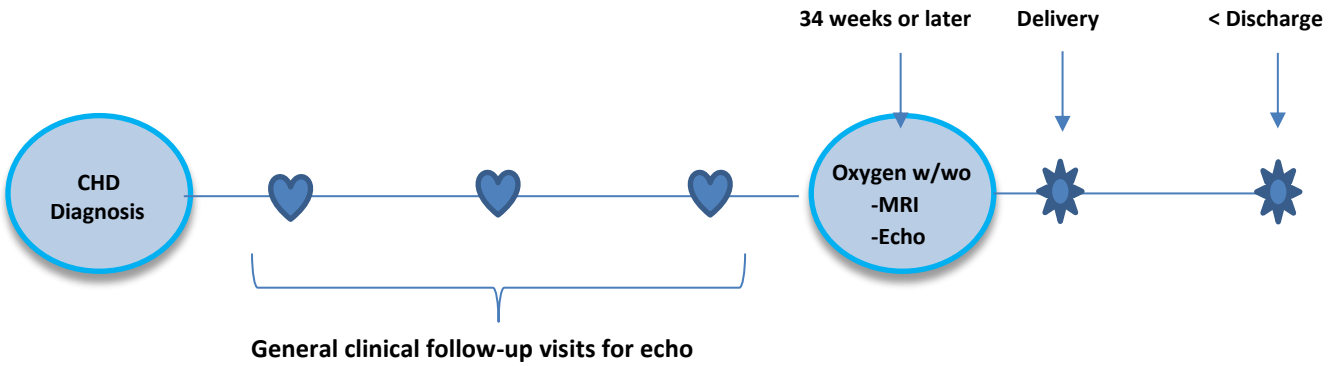
Study Visits
At the final pregnancy visit, the following will be done:

A fetal echocardiogram before and during oxygen administration – the scan will take about 60 minutes in total and will take place in the Fetal Echolab or the Cardiac Diagnostic and Intervention Unit (CDIU) on the 4th floor at SickKids.

A fetal MRI before and during oxygen administration – the scan will take about 90 minutes in total and will take place in the CDIU on the 4th floor at SickKids.

The scans will normally be performed during normal working hours, or exceptionally on weekends during the day. If you are an in-patient and need transport in a wheelchair or on a bed, this will be arranged. Please avoid eating for 2 hours before the MRI scan. There are no specific restrictions for the echocardiogram.

We will first examine your baby's heart and blood flow during the scans before you are given oxygen. We will then ask you to breathe in oxygen either through a mask. After about 5 minutes of oxygen, we will begin to re-examine the fetal heart and blood flow. These recordings will take a maximum of 20 minutes. The duration of oxygen administration will be a maximum of 30 minutes for the echocardiogram and 45 minutes for the MRI. At this stage, the oxygen will be stopped, the findings will be reviewed by the cardiologist, and then explained to you and your partner.



What are the risks, harms or discomforts of the study?

Echocardiograms and MRI: Both imaging tools are used routinely at our and other centers during the pregnancy and there are no known harms that may affect you and your baby. There are however situations a mother should not undergo an MRI scan, like having a pacemaker or if you are claustrophobic. We will check for any such conditions when you consider participation in this study.

Oxygen: No harmful effects of maternal oxygen therapy have been reported if oxygen is used briefly as a diagnostic test or prolonged to treat a baby.

Discomfort and Inconveniences: If you decide to participate in the study, the time of your echocardiogram and MRI will double in duration to about an hour or less for each test. We will try to schedule the echocardiogram and MRI at the same time and without much wait time but this may not always be possible. Lying still in the MRI scanner or on the bed for the echocardiogram as well as pressing on your tummy with the ultrasound scanner can become uncomfortable. We can usually resolve or at least improve this by allowing you to move from time to time and scan from different angles and positions on your tummy.

There may be other risks that we do not know about yet.

Are there benefits from being in the study?

This study uses a new approach to better identify newborns with TGA and a rapid need of treatment at birth. At this stage, we consider every baby with TGA to carry such a risk and will take all the possible precautions and measures to limit the risk of your child related to the heart disease. There may therefore not be a direct benefit from taking part in this study to you and your child.

If the results of the study confirm that maternal oxygen is useful to accurately predict the need of immediate treatment at birth, this will significantly benefit other families with a child with TGA e.g. by being able to provide the appropriate clinical care earlier on or consider an intervention even before birth.

Can I and my baby choose to leave the study?

You can change your mind at any time during the research study. You do not need to give a reason to withdraw from the study. Withdrawal from the study will not have any effect on the care you or your family will receive at SickKids. If you decide to leave the study, you can contact the Principal Investigator or a member of the study team to let them know.

If you decide to withdraw you and your baby from the study, we ask that you contact Dr. Edgar Jaeggi or another member of the study team to let them know that you are leaving the study. You can contact Dr. Jaeggi in person, by phone (416) 813-7466) or by email (edgar.jaeggi@sickkids.ca).

If you withdraw from the study, no new data about you will be collected for study purposes. Data that have already been collected for study purposes will be used for study reports and may be seen by SickKids Clinical Research Monitors, Research Team members of SickKids Diagnostic Imaging department, or the regulator of the study may see your health record and collect information relevant for the study.

Can participation in this study end early?

If the study doctor decides to withdraw you from the study, the study doctor may take you out of the study if:

- Sponsor and/or Funder end the study early
- You fail to follow study procedures.
- Termination of pregnancy
- There may be other reasons to take you out of the study that we do not know at this time.

How will your and your baby's privacy be protected?

We will respect your privacy. No information about your or your baby will be given to anyone or be published without your permission, unless the law requires us to do this.

The SickKids study staff (study investigators, coordinators, nurses and delegates) will collect personal health information about you and your baby. This includes things learned from the study procedures described in this consent form and/or information from you and your baby's medical records. They will only collect the information they need for the study.

All personal health information or personal information collected about you and your baby will be "de-identified" by replacing you and your baby's identifiable information (i.e., name) with a "study number". The SickKids study staff are in control of the study code key, which is needed to connect you

and your baby's personal health information/personal information to you. The link between the study number and you and your baby's identity will be safeguarded by the SickKids study staff. SickKids guidelines include the following:

- All information that identifies you or your baby, including paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
- No information identifying you and your baby will be allowed off site in any form without your consent. Examples include you and your baby's hospital or clinic charts, copies of any part of you and your baby's charts, or notes made from you and your baby's charts.

The study will also collect personal information that could identify you and your baby, such as:

- Date of birth
- Gender
- Cardiac diagnosis
- New or existing medical records, that includes types, dates and results of medical tests or procedures

The study staff and the others listed above will keep the information they see or receive about you and your baby's confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

Access to your and your baby's personal health information will take place under the supervision of the Study Doctor. You have the right to access, review and request changes to your personal health information.

The following people may come to the hospital to look at you and your baby's personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the SickKids Research Ethics Board and/or Research Quality and Risk Management team;
- Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada

The study staff will keep any personal health information about you in a secure and confidential location for 25 years after completion of the study and then destroy it according to SickKids policy.

When the results of this study are published, you and your baby's identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

Your and your baby's participation in this study will be noted in you and your baby's hospital or clinic chart. This is recommended to ensure your and your baby's safety so that any treating physician will know that you and your baby are participating in a research study.

Will it cost you anything to be in this study?

Participation in this study will not involve any additional costs to you and your baby.

You and your baby will not be paid or reimbursed for any expenses related to being in this study.

Will information about this study be available online?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if I or my baby are injured during/in this study?

If you or your baby suffer an injury from participation in this study, medical care will be provided to you and your baby in the same manner as you or your baby would ordinarily obtain any other medical treatment. In no way does signing this consent form waive your and your baby's legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

If you or your baby require treatment for any injuries or illness related to you and your baby's participation in the study, or if you or your baby suffer side effects while on a study drug, you should contact the study doctor as immediately.

How will I be informed about new information?

We may learn new information during the study that you may need to know. We can also learn about things that might make you and your baby want to stop participating in the study. If so, you will be notified about any new information in a timely manner. You may also be asked to sign a new consent form discussing these new findings if you decide to continue in the research study.

What if a researcher discovers something about me or my baby?

During the study, the researchers may learn something about you and your baby that they didn't expect. For example, the researchers may find something that is unexpected but important on the MRI scan or echocardiogram. Both the echocardiogram and MRI scan that are being done during oxygen administration are being done for research purposes and are designed to answer research questions, not to examine your or your baby's brain medically. This MRI scan or echocardiogram are not a substitute for one that a doctor would order, and they may not show problems that would be picked up by a medical MRI or echocardiogram scan. However, in the unlikely event that we note an atypical finding on either your or your baby's MRI scan, we will contact you to help you arrange medical follow-up to interpret the significance of the findings, if any. We may also ask a radiologist, cardiologist or other health professionals, to look at your or your baby's scan and by signing this consent form you agree to the release of the scan for review. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found. If atypical findings are found, the study doctors will contact your SickKids physician to report the findings and recommendations. Your physician will follow up with you and provide care as needed.

What are your and your baby's rights when participating in a research study?

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right, throughout the study, to ask questions about this study and to have them answered to your satisfaction, before you make any decisions.

Your and your baby's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your and your baby's privacy is respected.

You have the right not to sign this form permitting us to use and share your and your baby's health information for research. If you do not sign this form, you cannot take part in this study. This is because we need to use the health information of everyone who takes part in this study.

You have the right to withdraw your permission for us to use or share your and your baby's health information for this study. If you want to withdraw your permission, we ask that you contact a member of the study team to let them know that you are leaving the study. Your decision to leave the study will not affect your access to health care at The Hospital for Sick Children.

If you withdraw your permission, you and your baby cannot continue to take part in this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the study or to be sure the research is safe and of high quality.

By signing this form you do not give up any of your or your baby's legal rights against the study doctor or involved institutions for compensation, nor does this form relieve the study doctor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

Who can I call if I have questions about the study?

If you have any questions during the participation of this research study you can contact the Study Doctor, Dr. Edgar Jaeggi at (416) 813-7466.

Research Ethics Board Contact information

The study protocol and consent form have been reviewed by the SickKids Research Ethics Board.

If you have any questions regarding your or your baby's rights as a research participant, you may contact the Office of the Research Ethics Board at 416-813-8279 during business hours.

Future Research Studies:

We may do future research studies and want to know if we can use the data obtained from this study for future cardiac related studies. Please initial next to your preference:

Initial	Options:
_____	Yes, I agree for my and my baby's research information collected in this study to be used for other future cardiac related research studies
_____	No, I do **not** agree for my and my baby's research information collected in this study to be used for other future cardiac related research studies.

We may do future cardiac related research studies and want to know if we can contact you about these studies in the future. Please initial next to your preference:

Initial	Options:
_____	Yes, you can contact me regarding future cardiac related research studies.
_____	No, I do not want you to contact me regarding future cardiac related research studies.

Consent to Participate in a Research Study

Study Title: Transposition of the Great Arteries: Prenatal Anatomical and Hemodynamic Findings associated with Perinatal Outcomes

By signing this research consent form, I understand and confirm that:

1. All of my questions have been answered.
2. I understand the potential harms and benefits of participating in this study.
3. I know what I could do instead of taking part in this study.
4. I understand that I have the right to refuse to take part in this study. I also have the right to withdraw myself and my baby from the study at any time.
5. My decision to not take part in this study will not affect my or my baby's health care at SickKids.
6. I am free now, and in the future, to ask questions about this study.
7. I have been told that my and my baby's medical records will be kept private except as described to me.
8. I understand that no information about me or my baby will be given to anyone or be published without first asking my permission.
9. I understand the information within this informed consent form.

I consent to participate in this study.

Printed Name of Participant	Participant signature	Date

Printed Name of person who obtained consent	Signature	Date	Time

Role of person obtaining consent

I attest that I am not involved in the research study, I was present during the consent discussion and that the consent process was accurately explained to, and apparently understood by the participant. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____	_____
Print Name of Witness to the consent discussion	Signature of Witness and date (MMM, dd, yyyy)

_____
Role of person assisting in the consent process at SickKids

The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

_____	_____
Print Name of Interpreter	Signature & Date (MMM, dd, yyyy)

_____
Language