Adolescent Information and Assent Form

Adolescents aged 14+ years

The PORPOISE Study

Pediatric Outcomes and Recovery with Peri-Operative Iron Supplement Evaluation

A study to learn whether added nutrition is better for patients who are having varus-derotational osteotomy surgery

Who is in charge of the study?

The doctor in charge of this study is Dr. Teresa Skelton. She is being helped by other doctors and researchers. They will answer any questions I have about the study. I can also call them at 604-875-2711.

Invitation

I am invited to be in this study because I am scheduled for a varus-derotational osteotomy (VDRO) surgery at the BC Children's Hospital. It is up to me if I want to be in this study. No one will make me be part of the study, and no one will get mad at me if I don't want to be a part of this study.

Do I have to be in this study?

I do not have to be in this study if I don't want to. If I choose to be in this study, I can stop being in it anytime. The doctors and nurses will care for me as they have in the past, whether I am in the study or not.

If I want to be in this study, I will be asked to sign this form. My parent/guardian will need to sign a consent form before I become part of the study the study. I do not have to be in the study, even if they sign the consent form. The researchers will not put me in the study unless I agree.

I should read this form carefully and talk it over with my family and, if I wish, with my doctor before I decide. I can talk to the study doctors and researchers if I have any questions. I can choose to be in the study, not be in the study, or take more time to decide. Even if I agree now to be part of the study, I can change my mind later. I can ask the study doctors or researchers any questions I have during the study.

Why are we doing this study?

I am having varus-derotational osteotomy (VDRO) surgery. This happens to other children and young adults too. This study is trying to make a nutrition plan for children and young adults

having VDRO surgery. Nutrition is the foods and liquids that I eat and drink. This study is also trying to find out if I have enough iron in my blood. Iron is an element that everyone has in their blood. Sometimes, children and young adults having VDRO surgery don't have enough iron in their blood. This study wants to find out if better nutrition, which might include an iron treatment plan, will help patients like me feel better after our VDRO surgery.

Why are you inviting me to be in this study?

I am invited to be in this study to help find out if making my nutrition better might make me healthier before my VDRO surgery and might my recovery better after my VDRO surgery.

What will happen to me in this study?

If I decide to be in this study, I will meet with a dietitian for about 30 minutes. A dietitian helps me with my nutrition. A dietitian might help change my nutrition during the months before my surgery to make me healthier before I come to the hospital for my surgery. The dietician will check in with me and my family over the phone, for up to 30 minutes total. I will have my blood taken twice, to see if I have enough iron in my blood. It will take about 15 minutes each time I have my blood taken. My blood will be taken after I meet with the dietitian and again before my surgery. If I don't have enough iron in my blood, I might have to take iron tablets. I might have to eat different foods or drink different liquids, to make my nutrition better. My parents will fill out surveys, which will be sent to their email. There will be 3 surveys that will take 5 minutes each to ask how my family felt about the meeting with the dietician. If I take iron tablets, my parents will fill out a survey every month until my surgery. My family will also be able to do an interview while I am at the hospital recovering, if we want to. The interview will take about 30 minutes. The total time to participate in this study is between 1 hour and 45 minutes and 3 hours.

Can anything bad happen to me in this study?

If I have to take iron tablets, it might make my stomach hurt and cause constipation (hard poops). The study doctors have chosen a type of iron tablet that is less likely to make my stomach hurt. I might also feel a poke when I get my blood taken.

Will I benefit from being in this study?

I may not benefit from being in the study. The study doctors hope the information learned from this study can benefit future children and young adults like me having VDRO surgery. There might be a benefit from having better nutrition or from taking iron, but it is not known for sure yet.

Who will know that I am in this study?

My privacy will be respected. The study team will only tell people that I am or have been a part of this study if I allow them to. They will not release any information that could identify me to anybody else unless they have to by law.

To protect my privacy, the study team will remove any information that may be used to identify me from any study documents. Instead of my name appearing on them, I will be identified by a number that applies only to me. This number will be used on any research-related information collected about me for this study so that my identity as part of the study will be kept completely private. Only Dr. Teresa Skelton and her research team can link this number with my personal information. The linking information will be kept in a password-protected file on the data servers of BC Children's Hospital.

What will this study cost me?

All research-related care, treatment, and tests I receive during this study will be free. If I have to take iron, it will be given to me for free. Participating in this study will not cost me anything. Parking or transportation to the hospital may cost extra. My family will be given a $25 Starbucks gift card to thank us for participating in this study. If my family decides to participate in the interviews, we will receive a second $25 Starbucks gift card.

Who do I contact if I have questions about the study during my participation?

If I have any questions or desire further information about this study before or during participation, I can contact Dr. Teresa Skelton at (604) 875-2711.

Who do I contact if I have any questions or concerns about my rights as a participant?

If I have any concerns or complaints about my rights as a research participant, my experiences while participating in this study, or my privacy, I should contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll-Free: 1-877-822-8598). I should reference the study number H25-00010 when contacting the Complaint Line so the staff can better assist me.

Assent to Participate

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My signature on this assent form means:

- I have read and understood this assent form.
- I have had enough time to consider the information in this form and ask questions if I have them.
- I have been able to ask questions and have gotten answers.
- I understand that all personally identifying information collected will be kept confidential.
- I understand that de-identified data may be shared or made publicly available and that the results will only be used for scientific purposes.
- I understand that my participation in this study is my decision and that I am free to choose not to participate or leave this study at any time without changing the quality of care I receive.
- I can keep asking questions at any time about my participation in this study.
- I understand that if I put my name at the end of this form, I agree to be in this study.

I will receive a signed copy of this assent form.

I agree to participate in this study.

Printed Name	Signature	Date