PARTICIPANT CONSENT AND INFORMATION FORM

The PORPOISE Study

Pediatric Outcomes and Recovery with Peri-Operative Iron Supplement Evaluation

(H25-00010)

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If you are a parent or legal guardian of a child who may participate in this study, permission from you and your child's assent (agreement) may be required.

When we say "you" or "your" in this consent form, we mean you or your child; "we" means the doctors and other staff.

Invitation
You are invited to take part in this research study because you are scheduled to have a varus-derotation osteotomy (VRDO) surgery at the BC Children's Hospital.

Your participation is voluntary.
Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient, all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant, you and your doctor also must take into account the requirements for the research study. These may include procedures and treatments that are not part of standard practice or are not yet proven. This consent form describes the diagnostic and treatment procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

Who is conducting this study?
Dr. Teresa Skelton, the Pediatric Anesthesia Research Team, and the Department of Orthopedic Surgery are conducting this study as part of the BC Children's Hospital Research Institute.

Background
Varus-derotation osteotomy (VDRO), which may sometimes involve a pelvic osteotomy, is a surgery to prevent or address hip displacement in children. VDRO is a long surgery, often lasting more than 4 hours. A pelvic osteotomy involves reshaping the hip socket, to improve the fit of the hip joint. During this surgery, between 10% and 25% of patients need a blood transfusion. Some patients having VDRO surgery may be malnourished and have low amounts of iron in their blood, which is known as anemia. Malnutrition and anemia in children can affect their need for blood transfusions during surgery and how long they have to stay at the hospital after their surgery. Improving a patient's iron intake and nutrition before surgery might lead to a lower chance of needing a blood transfusion and a shorter stay in hospital. Currently, only patients with neuromotor conditions, such as cerebral palsy, receive comprehensive nutrition care.

What is the purpose of the study?

A “pilot study” or “feasibility study” is done to test the study plan and to find out whether enough participants will join a larger study and accept the study procedures. This type of study involves a small number of participants and is not necessarily expected to prove effectiveness. The results may be used as a guide for larger studies, although there is no guarantee that they will be conducted. Participation in a pilot study does not mean that you will be eligible to participate in a future larger study. Knowledge gained from pilot or feasibility studies may be used to develop future studies that may benefit others.

The goal of this study is to create a nutrition and anemia treatment plan for patients who are having VDRO surgery. Our goal is to find out whether our nutrition guidance and iron treatment for patients will lead to fewer blood transfusions and shorter hospital stays. We plan to use the results from this study to help patients who are having other types of surgery. We also aim to show that collaboration between nutrition, anesthesia, surgery, nursing, and physiotherapy can improve the care we provide for our patients.

Who can participate in this study?

We aim to recruit 50 to 60 patients. You may be eligible to participate in this study if:

- You are between 0 and 18 years of age.
- You are scheduled to have VDRO surgery.

You may or may not have a diagnosis of a neuromotor condition.

Who should not participate in this study?

You will not be eligible to participate in this study if:

- You have had a major surgery in the last 3 months.
- You have received a nutritional intervention that included iron testing and treatment in the last 3 months.
- Oral/enteral iron supplementation is not recommended by your doctor or dietician.
- You have a bleeding disorder.
- You are taking erythropoietin.

What does the study involve?

If you decide to participate in this study, your nutrition will be assessed by a dietitian. The dietician assessment will take about 30 minutes. The dietitian will help you plan your nutrition in the months leading up to your surgery. The dietician will check in with me through a phone call as required, for up to 30 minutes total. The study will ask you to have two blood tests to

check your iron levels. We will do this once right after your initial assessment and once just before your surgery. Each blood test will take about 15 minutes. Each blood sample will take between 2 and 4 milliliters of blood, which is about half a teaspoon to one teaspoon of blood. The dietician will look at your blood test results and inform you of the implications.

If we find out that you have low iron or anemia, you will be prescribed iron to take in the months leading up to your surgery. The form and dosage of iron will be determined by your dietician and by the results from your blood test. The typical dose of iron for pediatric patients with deficiency is 3-6 mg/kg, up to a maximum of 150 mg/day.

We will ask you to fill out some short online surveys and will ask you to provide us with an email address so we can send them to you. We will ask you to fill out three family satisfaction surveys: one week after your meeting with the dietitian, one week before surgery, and one week after surgery. If you have been prescribed iron, we will send you one survey each month leading up to your surgery to ask about whether you have been able to take the iron supplements and about any changes you have made to your diet. Each survey will take about 5 minutes. Finally, while you are at the hospital for your surgery, we will invite you to participate in an optional interview to ask about your opinions on the nutrition program and any potential improvements to the program. The interview will take about 30 minutes. The total time to participate in this study ranges from about 1 hour and 45 minutes to 3 hours.

What are the possible harms and discomforts?

The iron supplement we will prescribe is used commonly, but some children find that iron supplements can cause stomach discomfort, including constipation. We have an experienced clinical dietitian on our team, who will help lower this risk. The type of iron supplement prescribed is called “FeraMAX”. This was chosen because it has less effects on the stomach and can be taken with food. Blood tests are common and safe, but there may be some discomfort when having blood taken. In most cases, patients having VDRO surgery would have blood taken whether or not they participate in the study. However, participating in the study means that they will have their blood taken twice, which may be once more than they otherwise would. Having a blood test involves a needle, patients may feel an uncomfortable poke.

What are the potential benefits of participating?

There may not be a direct benefit to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other children undergoing VRDO and other types of surgery.

What are the alternatives to the study treatment?
If you do not want to participate in the study, you are still eligible to receive an optional nutrition assessment and management. If needed, you would still be eligible to receive iron supplementation.

What if new information becomes available that may affect my decision to participate?
If new information becomes available that may change your decision to participate, you will be informed of this by research team members. You may decide to leave the study at any time.

What happens if I decide to withdraw my consent to participate?
You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw later, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note, however, that there may be exceptions where the data will not be able to be withdrawn, for example, where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let the study doctor know. Should you choose to withdraw, there will be no impact on your clinical care.

How will my taking part in this study be kept confidential?
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the study doctor or their designate by representatives of the University of British Columbia / Children's and Women's Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

Because this is a treatment study, your signed consent form will be included in your electronic medical record, and your healthcare team will be alerted that you are on a study. This is to ensure your healthcare team has a little information about the study so that they can treat you safely according to the study protocol.

Will my data be used in the future?

Your de-identified research data (which means your name, birthdate, and other identifiers have been removed) may be deposited into a publicly accessible location at the time of publication. This can enhance the transparency of the research data and allows for external validation and fraud control, but it also allows others to access the data for re-analysis of this study or to do other kinds of analyses in the future beyond those you are consenting to in this study. Also, this future use of your data may not be subject to oversight by a research ethics board, and thus the data may be publicly shared and used in currently unknown ways. Once the data are made publicly available, you will not be able to withdraw your data nor will your child have the chance to individual consent to this use at the age of majority. Even though the identifying information will be removed from the data it is possible that others may be able to find out who you are. The chance of this is currently thought to be quite low. Should you not be interest, you may decline the future use of your data on the last page of this consent form.

What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you.

What will the study cost me?

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you. If iron supplementation

is prescribed, it will be covered by the "At Home" program or by our research team grant. The only additional costs to you for participating in this study will be the additional parking costs because you will be at the hospital for longer to participate in the nutrition assessment and to receive blood work. Your family will receive a $25 Starbucks gift card to compensate you for these possible extra costs. You will not receive any additional payment for your participation in this study. If your family chooses to participate in the optional interview, you will receive a second $25 Starbucks gift card.

If I have questions about the study procedures during my participation, who may I speak to?
If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Dr. Teresa Skelton at (+1) 604-875-2711 or by email at teresa.skelton@cw.bc.ca.

Who do I contact if I have any questions or concerns about my rights as a participant?
If you have any concerns or complaints about your rights as a research participant, your experiences while participating in this study, or any privacy-related complaints, 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.) Please reference the study number H25-00010 when contacting the Complaint Line so the staff can better assist you.

After the study is finished
De-identified study results, publication(s), a lay summary, and an infographic may be available after the study. If you choose to provide us with your email, we will share our results with you. You will also be able to obtain general information on the progress of this research project by visiting our website at http://part.bcchr.ca.

How will the research team contact me?
We may use your email or your phone number to communicate about this research study, depending on your preference. The research team will use their best efforts to keep your information confidential. However, there are always some risks of disclosure when using email and you should be aware that some email services may store the contents of your email account outside of Canada, where privacy and data security standards may be different than they are in Canada. If you have questions or would like to stop receiving research communication via email, please contact Dr. Teresa Skelton at (+1) 604-875-2711 or by email at teresa.skelton@cw.bc.ca.

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[H25-00010]

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights due to signing this consent form.
- I understand that there is no guarantee that this study will benefit me.
- I understand that the research team will contact me by telephone.

This consent form was read by the parent(s)/guardian(s)/substitute decision-maker (legally authorized representative), and both the person reading this consent form, and the investigator are satisfied that:

- The study information was accurately explained to and apparently understood by the child/participant.
- The child/participant was allowed to ask questions, and all questions have been answered.
- The child participant assents to participate in the research.

I allow my de-identified data to be used in the future or to be made publicly available.
☐Yes ☐No

I consent to participate in this study. I will receive a signed and dated copy of this consent form for my records.

Participant's Name	Parent/Guardian's Email	Phone Number
Parent/Guardian's Signature	Parent/Guardian's Printed Name	
Relationship to Participant	Date	

Signature of Person Obtaining Consent	Printed Name	Study Role	Date