Direct Peritoneal Resuscitation in Gastroschisis

12/20/2018

NCT03205553

Informed Consent and Authorization to Share Protected Health Information in Research

Study Title: Direct Peritoneal Resuscitation in Gastroschisis

Principal Investigators:

Sub-Investigator:

INTRODUCTION

You are being asked to give permission for your infant to take part in a research study. Taking part in research is voluntary. Please take time to make your decision, and discuss it with family and friends. This form provides a summary of the information the researchers will discuss with you. In order to decide whether or not you wish your child to be a part of this study, you should know enough about any risks or benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research including its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. Be sure to ask any questions you may have. Once you understand the study, you will be asked to sign this form if you wish your infant to participate. You will be given a copy of this form to keep as a record.

Why is this research study being done?

You are being asked to allow your infant to take part in this study because your infant has a condition called gastroschisis (GS). Before your infant was born, the bowel (intestines) grew outside of his/her belly. With this condition, there is increased risk of injury to the bowel. Not all infants suffer damage under these circumstances, and we are not certain that your infant has suffered any bowel injury.

The standard treatment for infants with GS is to place the bowel in a special plastic bag called a silo. Each day the bowel is pushed further into the belly. By day four or five, the bowel is in the belly enough to close it up.

Washing the bowel with warmed fluid may reduce the damage to the bowel. This process is called Direct Peritoneal Resuscitation (DPR). We do not know for certain if washing the bowel with fluid improves bowel damage. The purpose of this study is to test whether this warmed fluid (dialysate) safely improves return of bowel movements in patients with gastroschisis. Currently, dialysate fluid (a cleansing fluid used to remove waste products from blood when the kidneys no longer work properly) is not FDA approved for use in this way.

How many infants will take part in this study?

Up to 40 infants will take part in this study. Study infants will be enrolled at Arkansas Children's Hospital (ACH).

PROCEDURES

What is involved in the study?

If your infant qualifies for this study and you decide to be in this study, these things will happen:

- **Randomization:** One group of infants in this study will receive the bowel washing with warmed fluid called DPR. The other group will receive standard treatment. Your infant will be randomly assigned to one of these two groups. This means that your infant will have a 50/50 chance (like flipping a coin) of being assigned to either DPR group or the standard care group. Neither the researchers nor you will make the choice of which group your infant is in.

- **DPR Group:** If your infant is in the DPR group of the study, a silo will be placed at time of birth to cover the bowel. A set amount of warmed fluid will be placed into the silo surrounding his/her bowel using a special tube called a drain. This will be performed every 6 hours until the belly is closed. One hour after washing the bowel with warmed fluid, the fluid will be removed from the silo by using the drain. Within four to five days, the infant will be taken to the operating room to close the abdomen.

- **SoC Group:** If your infant is in the SoC (Standard of Care) group, a silo will be placed at time of birth to cover the bowel. He/she will not be given bowel washing with warmed fluid. Within four to five days, the infant will be taken to the operating room to close the abdomen.

- **Blood samples:** All infants will have a small amount of blood taken for regular care each day, up to 1 mL (approximately 1/6 to 1/5 of a teaspoon). A small amount of blood, up to 2 mL (approximately 1/2 to 3/5 of a teaspoon), will also be collected for research.

  For the SoC group, one additional research blood sample will be drawn once each day at the same time blood is taken for regular care.

  For the DPR group, the research blood samples will be drawn once at the same time blood is taken for regular care and then approximately every 6 hours until 24 hours after the DPR is finished. Then, the research blood samples will be taken once approximately every 12 hours until the day after the belly is closed. A glucose (blood sugar) test will also be done 1 hour before and 1 hour after each time the bowel is washed with warmed fluid for the first day. When possible, these will be done at the same time of other research labs.

- **Ultrasound:** All infants will have daily ultrasounds performed on the abdomen starting the day after the operation to close the abdomen until we start feeding. This will help us to see how the intestines are moving using the ultrasound but we will not make any changes to their feeding schedule based on the findings. We will use the usual clinical indicators that are already in place in the NICU for the feeding schedule.

- **Medical record review**: We will collect information from your infant's medical record, including birth date, gender, mother's zip code, mother's race, mother's history of substance abuse, results of drug screens for mother and infant at birth, prenatal care, birth weight, body length, head circumference, pregnancy and birth history, diagnostic tests, medical diagnoses and treatments related to your infant's hospital course.

Safety testing during the research study

The principal investigator, , or her staff will tell you about any new information that we learn that may affect your infant's health, welfare, or your willingness to allow your infant to stay in the study.

How long will my infant be in the study?

Your child's active involvement in the study will end after up to eight days. The silo is commonly left in place for up to the first seven days of life and then the belly is closed. We will continue to collect information about your child throughout his/her stay in the hospital. We will follow-up on how your infant is doing one time up to 90 days after he/she is released from the hospital with either a review of the medical record (if available) or a phone call.

Can my child stop being in the study?

You can decide that your infant should stop taking part in this study at any time. If you decide to stop contact at or 24-hour phone via cell at . Please talk with the research doctor so your infant is taken out of the study in a way that will be safe. If you leave the study, your infant's test results and information that has already been collected before you withdraw cannot be removed from the study records.

The study doctor or your infant's doctor may take your infant out of this study at any time. This would happen if:

- They think it is in your infant's best interest not to continue with the study.
- Your infant is not able to make the required study visits.
- The whole study is stopped.

Who will see the information about me that is collected?

- The local study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are in the study.
- We will take your name off information that we collect from you during the study.
- When we share the results of the study in medical journals, we will not include your name in the writing of the study.
- There are people who make sure the study is run the right way. The following groups may see information from the study about you:
  - Study Staff
  - Food and Drug Administration (FDA)
  - The Arkansas Children's Research Institute (ACRI) and the University of Arkansas for Medical Sciences (UAMS) Research Compliance offices
  - Office of Research Regulatory Affairs (ORRA)
  - Office for Human Research Protections (OHRP), a federal agency
  - UAMS Institutional Review Board (IRB)
  - Other institutional oversight offices
- State law requires we tell the authorities if we learn:
  - about possible child or adult abuse
  - that you might hurt yourself or someone else

Where and how long will my information be kept?

- We will code your information and keep the code on a password protected computer.
- Only study personnel will have access to the code for your information.
- Study data will be kept for as long as required by our institutional policy, which could be up to 23 years, after the completion of the study.
- Blood samples will be collected each day for the length of time described previously. They will not be maintained in the lab for future use.
- We will put a copy of this form in your medical record.

What are the risks of taking part in this research study?

Every infant taking part in the study will be watched carefully for side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious.

- **DPR risks:** Risks for babies who undergo DPR treatment include scar tissue formation in babies' abdomens, allergic reactions to corn, and possible reactions to blood sugar medication or other medication and treatments. Additional risks include changes in the infant's blood lab numbers (changes in blood pH, low or high blood volume, low blood salt, low

chloride, low potassium) which will be monitored via daily labs, fungal or bacterial infections of the abdominal cavity, catheter related infections, excess fluid in body tissues, dehydration, low or high blood pressure, difficulty breathing, cloudy dialysis fluid during treatment, vomiting, nausea, diarrhea, constipation, belly pain, belly swelling, uncomfortable feeling in the belly, Stevens-Johnson syndrome (a rare, serious disorder of the skin and mucous membranes that causes painful blisters and sores), hives, rash that may itch or occur all over the body, itching of the skin, muscle pains, muscle spasms, bone pain, swelling, fever, feeling unhealthy, infusion site reactions and catheter related complications.

- **Randomization**: Your infant will be assigned to either a DPR treatment group or standard care group by chance.

- **Blood collection:** There is a risk of bruising, pain, and bleeding.

- **Unknown Risks:** The study treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

- **Confidentiality:** Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured by keeping all paper study forms in a locked office and any electronic study forms on a password-secured computer. As with any use of electronic means to store data, there is a risk of breach of security data. Your child's name will not be used in any reports from research performed using her/his samples. More information about confidentiality is in the "Authorization to share protected health information in research" section below.

  A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Who to contact for questions

You may contact or someone else on the study team for any questions, concerns, or complaints about the research by calling or 24-hour phone via cell at and asking for or one of the other doctors listed on the first page of this consent form. Should you have any questions regarding your child's rights as a research subject, you may contact the UAMS Institutional Review Board at 501-686-5667. You can also contact the IRB if you wish to speak with someone who is not associated with the study team.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your infant's health better. While doctors hope that DPR will be more effective than standard care at improving your infant's bowel function and decreasing bowel injury, there is no proof of this yet.

If your infant is in the group that receives DPR and it proves to be a better treatment for GS than the current standard therapy, your infant may benefit from participating in the study; however, this cannot be guaranteed. If your infant is assigned to the standard care group, there will be no direct benefit to your infant from participating in the study. However, it is hoped that the information gained from the study will help in the treatment of future infants with GS.

What other choices are there?

Taking part in this study is voluntary. If you choose not to allow your infant to participate in the study, s/he will continue to receive the best standard of care that all infants routinely receive. If your child does become a subject, you are free to withdraw him/her from this study at any time. If you withdraw your child from the study, it will not adversely affect your child's relationship with the doctors or this hospital.

How much will the study cost me?

Neither you nor your insurance company will be charged for taking part in this study. The costs of the research will be paid for by the study. This includes the costs of fluid for bowel washings, research blood tests and study procedures. We will bill you or your insurer for your infant's standard clinical care including the surgery.

Will my infant or I be paid to be part of the study?

There is no payment for being in this study.

In case of injury

In the event your infant is hurt by being in this research, treatment will be available. This treatment may include first aid, emergency treatment, and/or follow-up care. This treatment may be billed to you, or your insurance company, in the normal manner. Normally, no other form of compensation is available. If you think your infant has been hurt by this research, let the study doctor know right away by calling at any time at or 24-hour phone via cell at and asking for .

Authorization to share protected health information in research

The word "you" means both the person who takes part in the research, and the person who gives permission to be in the research.

We are asking you to take part in the research described in this form. To do this research, we need to collect health information that identifies you. We may collect information from you and your child's medical records. We will collect information from your infant's medical record, including birth date, gender, mother's zip code, birth weight, body length, head circumference, pregnancy and birth history, diagnostic tests, medical diagnoses and treatments related to your infant's hospital course. In addition, new information created during this study includes your child's response to DPR and side effects. This information will be used for the purpose of the research study described in this form. We will only collect information that is needed for the research. This information may be placed into your medical record at ACH. For you to be in this research, we need your permission to collect, create and share this information.

We will, or may, share your health information with people at Arkansas Children's Hospital who help with the research or things related to the research process, such as the study staff, UAMS IRB, the research compliance offices at ACRI and UAMS, ORRA, OHRP, FDA and other institutional oversight offices. We believe that those involved with research understand the importance of preserving the confidentiality of your health information. However, some of the people outside of ACH may share your health information with someone else. If they do, the same laws that ACH must obey may not apply to others to protect your health information.

If you sign this form, we will create, collect, use, and share your health information until the end of the research project. We will protect the information and keep it confidential.

If you sign this form, you are giving us permission to create, collect, use and share your health information as described in this form. You do not have to sign this form. However, if you decide not to sign this form, you cannot be in the research study. You need to sign the research consent form if you want to be in the research study.

If you sign this form but decide later that you no longer want us to collect or share your health information, you must send a letter to the Principal Investigator, , at the following address:

The letter needs to be signed by you, should list the "Study Title" listed on this form, and should state that you have changed your mind and that you are revoking your "HIPAA Research Authorization". You will need to leave the research study if we cannot collect and share any more health information. However, in order to maintain the reliability of the research, we may still use and share your information that was collected before the Principal Investigator received your letter withdrawing the permissions granted under this authorization.

If you decide not to sign this form or change your mind later, this will not affect your current or future medical care at Arkansas Children's Hospital/UAMS. Participation in this study does not waive any legal right that you/your child may be entitled.

The researcher will give you a signed copy of this form.

Parent's Statement

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I have been told that I will be given a copy of this consent form. No rights have been waived by signing the consent form.

The health information about _____ can be collected and used by the researchers and staff for the research study described in this form.

By signing below, I am giving my permission for my infant to be included in this study.

_____
Name of Infant

_____ _____
Signature of Parent or Legal Guardian Date

_____
Relationship to participant

_____ _____ _____
Witness* Date Time

**If the consent form is faxed to the parent/legal guardian for signature, a witness signature is required.*

☐ Not Applicable

_____ _____ _____
Person Obtaining Consent Date Time