INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Evaluation of Routine Administration of Glycerin Suppositories to Improve Bowel Function in Patients with Uncomplicated Gastroschisis

Your child is invited to participate in a research study evaluating glycerin suppositories in treatment of children with gastroschisis. He/she was selected as a possible subject because of this diagnosis. The pediatric general surgery team at Riley Children's Hospital is responsible for this study and is involved in the care of all neonates with this problem. Please read this form and ask any questions you may have before agreeing to be in the study.

The study is being led by Dr. Alan Ladd with the help of the rest of the pediatric general surgeons at Riley Children's Hospital (Drs. Billmire, Burns, Gray, Landman, Markel, Rescorla, and Rouse). It is internally funded by these physicians and the Indiana University School of Medicine Department of Surgery, Division of Pediatric General Surgery.

STUDY PURPOSE

Glycerin suppositories are often used in children with gastroschisis after abdominal wall closure with the goal of improving function of the intestines and decreasing the time it takes to start enteral feeds (i.e. using the intestines to absorb nutrition) and the time to reach goal feed volumes (i.e. the amount needed for your baby to grow appropriately). Reducing this time has been shown to improve outcomes in babies with gastroschisis. However, it is not known if using glycerin suppositories actually helps decrease this time. The purpose of this study is to determine whether routine use of glycerin suppositories improves bowel function as measured by the time to first bowel movement after abdominal closure and time to full enteral feeds.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree, your child will be one of approximately seventy subjects who will be participating in this research. One half of the patients will have a glycerin suppository administered daily beginning the day after their final surgery for gastroschisis, the other half will receive no glycerin suppositories at any point during their treatment. These two groups will then be compared based upon the factors mentioned above. Your participation in this study will complete at the time of initial discharge from the hospital.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will do the following things:

Your child will be randomly assigned to either receive daily glycerin suppositories as part of their treatment or receive no glycerin suppositories as part of their treatment. Suppository administration will begin the day after their final surgery until the day all needed nutrition is provided by breast milk and/or formula. The choice between breastmilk or formula will be left up to you/your child's caretakers. Additionally, a standard protocol for advancing feeds in babies with gastroschisis will be used. This protocol has been approved for this study by all of the pediatric general surgeons at Riley Hospital for Children. There will be no additional alterations in the treatment of your child compared to children with gastroschisis not involved in this study.

RISKS OF TAKING PART IN THE STUDY

While on the study, the risks, and side effects are:

-Injury to the rectum/large intestines while giving a suppository (while this has never occurred at Riley, it is a possible risk)
-Discomfort with suppository administration and/irritation to the intestines and surrounding skin with administration of the glycerin suppositories

-In premature neonates, necrotizing enterocolitis (a disease that causes lack of blood flow and injury to the intestines) has been reported after receiving glycerin suppositories. Premature neonates are at increased risk for necrotizing enterocolitis and no study has definitively linked suppositories to an increased risk of necrotizing enterocolitis in this population. This study will not include premature neonates and necroziting enterocolitis has not been reported in term neonates after receiving glycerin suppositories, but a possible increased risk cannot be excluded. Necrotizing enterocolitis is higly variable disease process; ranging from clinically insignificant to fatal disease.

-Loss of confidentiality with resultant difficulties in obtaining insurance and/or social/psychological stress to the patient and/or family

-There also may be other side effects that we cannot predict.

Measures that will be employed to minimize the risks and side effects listed above:

-All infants with gastroschisis are already monitored for signs of necrotizing enterocolitis. Any signs of enterocolitis (abdominal distention with associated fever/leukocytosis/other signs of infection) prompt additional work up. Any child diagnosed with necrotizing enterocolitis will be removed from the study protocol (i.e. glycerin suppositories will be stopped if in treatment group) and treatment of necrotizing enterocolitis will begin.

-While the possibility of rectal perforation/injury during administration of glycerin suppositories is possible, this has not been reported in the literature or occurred at our institution in children with gastroschisis. Nurses will be instructed to notify the research coordinator/surgery team if any significant rectal bleeding occurs during/after administration or if difficulty placing the suppository is noted. At that time it will be determined by the research team if the patient administration should be stopped (the patient will be removed from the study/protocol).

-Social/legal: All information will be de-identified as early as possible within the data acquisition period (i.e. removal of medical record numbers, date of birth, date of admission, etc.)

BENEFITS OF TAKING PART IN THE STUDY

The benefits to participation that are reasonable to expect are:

-If your child receives glycerin suppositories and this proves to be beneficial, they will have a proven decreased risk of problems during the hospitalization.

-Your child will be aiding in the improved treatment of future children with gastroschisis regardless of the treatment group they are assigned.

ALTERNATIVES TO TAKING PART IN THE STUDY

Instead of being in the study, you have these options:

-You may choose to not participate in this study and have your child’s feeding regimen and administration of glycerin suppositories determined by your personal surgeon.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Food and Drug Administration (FDA) who may need to access your medical and/or research records.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

COSTS

Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be responsible for the following costs:

-Potential increased cost related to medications. No additional laboratory studies or additional analysis/work up will be necessary.

PAYMENT

You will not receive payment for taking part in this study.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

FINANCIAL INTEREST DISCLOSURE

None of the research personnel have financial interests.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact a research member at 317-274-4681. If you cannot reach the researcher during regular business hours (i.e., 8 a.m. to 5 p.m.), please call the IU Human Subjects Office at 317-278-3458 or 800-696-2949. After business hours, please call the Riley Hospital for Children Surgeon's Office 317-944-5000 and ask for the pediatric surgeon on-call.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 317-278-3458 or 800-696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Riley Hospital for Children or your child's care teams.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances:

-Your child has an adverse reaction to glycerin suppositories (such as an allergic reaction, intestinal injury, or other intolerance) or if they are unable to advance enteral feeds based upon the established protocol

You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by Dr. Alan Ladd and/or your surgeon of record if information not available at the time of enrollment into this study suggests your child is at a greater than minimal risk as a result from participating in this study.

USE OF SPECIMENS

No specimens will be used in this study.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent for my child to participate in this research study.

I will be given a copy of this informed consent document to keep for my records.

Printed Name of Child:_____

Child's Date of Birth:_____

Printed Name of Parent:_____

Signature of Parent:_____**Date**:_____

If two (2) parents are required to sign the consent document:

Printed Name of Parent:_____

Signature of Parent:_____**Date:**_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date:**_____